EPA Jacket
92589-1

Decision #: 551035
DP #: (453017)
PRIA
Parent DP #:
Submission #: 1034761
E-Sub #: 39226

DATA PACKAGE BEAN SHEET

Date: 02-Jul-2019

* * * Registration Information * * *

Registration: 92589-R - BioBuster

Company: 92589 - ENVYSS, LLC

Risk Manager: RM 34 - Jacqueline Hardy - 703-308-8416 Room# PY1 S-8317

Risk Manager Reviewer: Lorena Rivas LRIVAS

Sent Date: PRIA Due Date: 06-Nov-2019 Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (A540) New end use product;FIFRA §2(mm) uses only;up to 25 public health organisms;

Ingredients: 013905, Sodium chloride(1.5%)

063604, Potassium peroxymonosulfate(21.41%)

* * * Data Package Information * * *

Expedite: ● Yes ○ No Date Sent: 28-Jun-2019 Due Back:

DP Ingredient: 013905, Sodium chloride

063604, Potassium peroxymonosulfate

DP Title: Acute Toxicology

CSF Included: ● Yes ○ No Label Included: ● Yes ○ No Parent DP #:

	Assigned To	Date In	Date Out	
Organization:	AD / PSB			Last Possible Science Due Date: 07-Oct-2019
Team Name:				Science Due Date:
Reviewer Name:				Sub Data Package Due Date:
Contractor Name:				

* * * Studies Sent for Review * * *

No Studies

* * * Additional Data Package for this Decision * * *

Can be printed on its own page

* * * Data Package Instructions * * *

PRIA: New Disinfectant
Electronic Submission - Pls go to Documentum for Info

Bridging:
Registrant is citing 778-91's acute tox data to support this product's hazard language. Is this acceptable?

& Need Review from Joseph.

All text in brackets [ ] is optional and may or may not be included on a final label

BioBuster
Broad Spectrum Disinfectant and Virucide
Deodorizer

Alternate Brand Names
BioBuster Disinfectant and Virucide
~~BioBuster Aquatic Disinfectant and Virucide~~
BioBuster Broad Spectrum Disinfectant
BioBuster VC Broad Spectrum Disinfectant for Veterinary Clinic Use
BioBuster VC Disinfectant and Virucide for Veterinary Clinic Use
BioBuster HD Disinfectant and Virucide for Ffarm Use
BioBuster Greenhouse Disinfectant and Virucide
~~BioBuster S Processing Facility Sanitizer~~
BioBuster FP Broad Sspectrum Disinfectant for Processing Facilities
~~BioBuster Air for Odor Control~~

[BROAD SPECTRUM DISINFECTANT,] [CLEANSANIER,] [VIRUCIDE,]] [& ALGAECIDE]. [Poultry Hatchery Disinfectant] [Farm Premise Disinfectant] [Veterinary and Animal Hospital Disinfectant] [For Poultry, Swine and Livestock Premises] [For Veterinary, Laboratory Animal, Kennel and Animal Breeder Facilities] [Effective in 400ppm Hard Water as CaCO3] [Disinfects in 5% Organic Soil Load] [For Greenhouse Facilities and Equipment] [For use in Horticulture] [Processing and Slaughter Plant Disinfectant] [For Aquaculture Facilities] [Routine CleaningSanitizing in Commercial and Industrial Facilities][~~For misting in the presence of poultry or swine to control the spread of airborne pathogens~~]

For Use in CleanSanitizing or Disinfecting Industrial, Commercial, Animal and Agricultural Facilities. BioBuster can also be used as a deodorizer.

Effective against:
Virus
Bacteria

ACTIVE INGREDIENTS:	
Potassium peroxymonosulfate	21.40+%
Sodium Chloride	1.50%
OTHER INGREDIENTS	77.10%
TOTAL	100.00%

KEEP OUT OF REACH OF CHILDREN
DANGER/PELIGRO

EPA Reg. No.
EPA Est. No.
Batch No:
Expiry Date:

FIRST AID	
If in Eyes:	Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after 5 minutes, then continue rinsing eye. Call a Poison Control Center or doctor for further treatment advice.
If on Skin or Clothing:	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a Poison Control Center or doctor for further treatment advice.
If Swallowed:	Call a Poison Control Center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor Do not give anything by mouth to an unconscious person
FOR EMERGENCY INFORMATION	
[For 24-hour emergency information on this product, call the poison control center 1-800-222-1222.] Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	
Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.	

Manufactured for:
EnVyss, LLC
178 Rowland Pointe
Morganton, GA 30560

BioBuster is effective against:

BACTERIA:

[Aeromonas spp.]
[Campylobacter jejuni]
[Escherichia coli]
[Mycoplasma gallisepticum]
[Pseudomonas aeruginosa]
[Salmonella enterica]
[Salmonella typhimurium]
[Staphylococcus aureus]
[Streptococcus suis]
[Vibrio anguillarum]
[Bordetella avium]
[Listeria monocytogenes]

VIRUSES:

Adenovirus: Pigeon Adenovirus[1], Bovine Adenovirus, Canine Aadenovirus (canine hepatitis), Duck Adenovirus, Egg Drop Syndrome, Duck Enteritis

Corona virus: Feline Infectious Peritonitis[1], Transmissible Gastroenteritis, Porcine Epidemic Diarrhea, Infectious Bronchitis, Canine Corona Virus

Herpes Virus: Avian Laryngotracheitis[1], Equine Herpes Type 3 (Coital Exanthema), Feline Rhinotracheitis, Feline Herpes, Marek's Disease, Turkey Herpes

Orthomyxovirus: Avian Influenza Virus H7N1[1], Swine Influenza

Parvovirus: Canine Parvovirus[1], Feline Panleukopenia Virus, Porcine Parvovirus, Mouse Parvovirus

Flavivirus: Bovine Viral Diarrhea Virus[1]

Circovirus[2]: Chicken Anemia, PCV2;
Calicivirus[2]: Feline Calicivirus;
Papilloma virus: Equine Papillomatosis
Paramyxoviruses[2]: Canine Parainfluenza, Canine Distemper, Turkey Rhinotracheitis
Parapox virus: Bovine Pseudocowpox
Picorna virus: Swine Vesicular Sstomatitis
Polyoma virus: Bovine Ppolyoma Vvirus
Reovirus: Avian Rreovirus
Rhabdovirus[2]: Snakehead Rhabdovirus and Vesicular Stomatitis Virus,
Rotavirus[2]: Calf Rotavirus

1= tested virus; 2 = Reliance on viral hierarchy for non OIE pathogens

[PLANT PATHOGENS]
[Botrytis cinera]
[Fusarium oxysporum]
[Penicillium oxalicum]
[Pythium aphanidermatium]
[Rhizoctonia solani]
[Sclerotinia sclerotiorum]

PRECAUTIONARY STATEMENTS:
Hazards to human and domestic animals.
DANGER. Powder is corrosive in concentrated form.
Causes irreversible eye damage or skin burns. Harmful if swallowed or absorbed through the skin. Do not get in eyes, on skin or on clothing. Wear protective eyewear, protective clothing and rubber gloves. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.
Corrosive statement refers to powder only and not to the product in use dilution.

ENVIRONMENTAL HAZARDS:

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

[BioBuster Virucide and Disinfectant is a complete, chemically balanced disinfectant formulated to be environmentally friendly and without concern of antimicrobial resistance. BioBuster Virucide and Disinfectant provides broad spectrum efficacy, killing gram positive and gram negative bacteria, virus, mycoplasma [and inhibiting the formation of slime and algae and associated slime forming bacteria] in industrial, animal and agricultural facilities and for use in greenhouses, horticulture and aquaculture. ~~[May be used as a routine sanitizer at a concentration of 0.5% (1:200).] [May be misted in the presence of poultry or swine to control the spread of airborne pathogens at a concentration of 0.5% (1:200).]~~

DIRECTIONS FOR USE
It is a violation of Federal law to use this product in a manner inconsistent with its labeling

GENERAL INSTRUCTIONS — FARM PREMISES, ANIMAL HOUSING BUILDINGS AND FARM EQUIPMENT

1. Remove all animals and feed from premises, vehicles and enclosures. Remove all litter and manure from floors, walls and surfaces of barns, pens, stalls, chutes and other facilities and

fixtures occupied or traversed by animals. Empty all troughs, racks, and other feeding and watering appliances.

2. Thoroughly clean all surfaces with detergent and rinse with water.

3. Saturate all surfaces with the appropriate disinfection solution. Surfaces must remain wet for 10 minutes.

4. Immerse all animal handling equipment and forks, shovels, and scrapers used for removing litter and manure in the appropriate disinfection solution for 10 minutes. Allow to air dry.

5. Ventilate buildings and other closed spaces. Do not house animals or livestock or use equipment until the disinfection solution has been absorbed, set, or dried.

6. Thoroughly scrub treated feed racks, troughs, automatic feeders, and waterers with detergent and rinse with potable water before reuse.

~~[Fogging (Wet Misting) Instructions]~~

~~All surfaces must be cleaned and disinfected in accordance with label directions prior to fogging. Fogging should be used a supplement to normal cleaning and disinfection practices and procedures.~~

~~Close room off, so fog is confined to the room to be treated. Ensure that the room is empty of people or livestock.~~

~~Prepare a stock solution of 0.5% to 2.0% in water (1:200 to 1:50) - (refer to specific directions for Poultry, Swine, Bovine, Greenhouse and Aquaculture uses.).~~

~~Apply the solution at an application rate of 1 gallon per 430 ft2 of floor space. Use a mechanical or plumbed in misting system designed for water based applications with a droplet size of greater than 50 microns, or a pressure washer/backpack or tank sprayer to deliver fine mist. Insert the nozzle of the fogging device through a suitable opening in the room. Do not allow people to breathe or contact the fog or to enter the room until the fog has completely settled or exhausted. Do not house animals or use equipment until treatment has dried. Rinse waterers and feeders with potable water before reuse. Rinse foggers and sprayers with potable water following use.~~

~~Note: Individuals must avoid entering the building or room during fogging. If the building or room must be entered, then individuals entering must wear a NIOSH/MSHA approved respirator, goggles and long sleeve shirts and pants.]~~

BIOBUSTER MIXING INSTRUCTIONS:

To mix the appropriate use-diluted solution of BioBuster, first identify the percent solution desired. Second, fill a clean container with the volume of water for the desired percent solution and then add the associated quantity of powder (using the provided scoop) found in the following table. One scoop (1.3 ounces of powder) added to one gallon of water will yield a 1% solution.

Quantity of Water	0.5% Solution	1% Solution	2% Solution
1 Quart	0.15 ounces	0.3 ounces	0.7 ounces
1 Gallon	0.65 ounces	1.3 ounces	2.7 ounces
10 Gallons	6.7 ounces	13.4 ounces	26.7 ounces
50 Gallons	33.4 ounces	66.8 ounces	133.5 ounces

Solutions are stable for 7 days. 10 minutes is maximum necessary contact time. One gallon of solution is sufficient to treat 135 sq. ft.

~~[BIOBUSTER MISTING/THERMAL FOGGING/COLD FOGGING INSTRUCTIONS]:~~

~~Application~~	~~Dilution Rate~~	~~Method~~
~~Misting/Fogging~~	~~1:200~~	~~Use a pressure washer or backpack sprayer on the finest setting and apply 1 liter of BioBuster solution per 10 square meters of floor space.~~
~~Cold Fogging~~	~~1:100~~	~~Use a misting apparatus to apply BioBuster at a rate of 1 liter per 10 square meters of floor space.~~
~~Thermal Fogging~~	~~1:25~~	~~Use a 4% solution of BioBuster in an 85:15 water/fog enhancer mixture. Using a thermal fogger, apply the solution at 1 liter per 10 square meters of floor space.~~

[WATER SYSTEM TANK DISINFECTANT]:

Application	Dilution Rate	Instructions
Terminal Disinfection	1:200 – 1:100	Isolate the header tank at the main. Drain the line. Clean out gross soiling and debris. Refill with water and add the appropriate volume of BioBuster, mix well and let sit for 10 minutes. Flush the system to all drain off points and let sit for another 50

		minutes. Drain the system and refill with clean water.
Continuous disinfection	1:1000	Dose the header tank as required or apply through water system dosing equipment.

[BOOT DIPS]:

[Use a 1% solution in boot baths for the routine disinfection of footwear. Replace the solution daily or more often if the solution becomes visibly soiled.]

[POULTRY PRODUCTION]:

[HATCHERIES: BioBuster at 1% solution can be used for cleaning and disinfecting hatchers, setters, evaporative coolers, humidifying systems, transfer trucks, trays, racks, carts, sexing tables and plastic chick boxes. Saturate surfaces with a 1% solution with a coarse spray, cloth, mop or sponge and let sit for a period of 10 minutes. Allow surfaces to air dry.]

~~[Fogging (Wet Misting) Instructions – Poultry and Ratite Production~~

~~All surfaces must be cleaned and disinfected in accordance with label directions prior to fogging. Fogging should be used a supplement to normal cleaning and disinfection practices and procedures.~~

~~Close room off, so fog is confined to the room to be treated. Ensure that the room is empty of people or livestock.~~

~~Prepare a stock solution of 0.5% to 2.0% in water (1:200 to 1:50) - (refer to specific directions for Poultry, Swine, Bovine, Greenhouse and Aquaculture uses.).~~

~~Apply the solution at an application rate of 1 gallon per 430 ft^2 of floor space. Use a mechanical or plumbed in misting system designed for water-based applications with a droplet size of greater than 50 microns, or a pressure washer/backpack or tank sprayer to deliver fine mist. Insert the nozzle of the fogging device through a suitable opening in the room. Do not allow people to breathe or contact the fog or to enter the room until the fog has completely settled or exhausted. Do not house animals or use equipment until treatment has dried. Rinse waterers and feeders with potable water before reuse. Rinse foggers and sprayers with potable water following use.~~

~~Note: Individuals must avoid entering the building or room during fogging. If the building or room must be entered, then individuals entering must wear a NIOSH/MSHA approved respirator, goggles and long sleeve shirts and pants.]~~

[BROILER/BREEDER HOUSES: Follow General Instructions to remove poultry and clean the area to be treated. Spray floors and walls with BioBuster at 1% solution. Thoroughly wash

waterers and feeders with a 1% solution of BioBuster. After contact for 10 minutes, rinse with potable water. Do not house poultry or use equipment until treatment has dried.]

~~[MISTING OVER POULTRY: Spraying a fine disinfectant mist in poultry housing can help reduce cross infection and prevent secondary infection during outbreaks of respiratory and other diseases. BioBuster can be misted in the presence of poultry at a dilution rate of 1:200 (0.5%).]~~

[PROCESSING PLANTS: Spray BioBuster at 1% solution to disinfect and clean walls, ceilings and floors. Saturate surfaces for a period of 10 minutes. Allow surfaces to air dry. ~~For routine sanitizing, apply BioBuster at a concentration of 0.5%.]~~

[SWINE PRODUCTION]:

[Follow General Instructions to remove swine and clean the area to be disinfected. Use a 1% solution of BioBuster for cleaning and disinfecting farrowing units, nurseries, finisher houses, processing plants, and agricultural production equipment such as trucks, rubber boots and associated livestock equipment. Saturate surfaces with a 1% solution with a cloth, mop, mechanical spray or sponge for a period of 10 minutes. Allow surfaces to air dry. Rinse waterers and feeders with potable water before reuse.]

~~[Fogging (Wet Misting) — Swine~~

~~Follow General Instructions to remove animals from room to be treated.~~

~~Use a 0.5% - 1.0% solution of BioBuster for fogging (wet misting) operations as a supplemental measure after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions. Rinse foggers and sprayers with potable water following use. Refer to Fogging (Wet Misting instructions)].~~

~~[MISTING OVER SWINE: Spraying a fine disinfectant mist in swine housing can help reduce cross infection and prevent secondary infection during outbreaks of respiratory and other diseases. BioBuster can be misted in the presence of swine at a dilution rate of 1:200 (0.5%).]~~

[EQUINE FACILITIES]:

[APPLICATIONS: For cleaning and disinfecting all hard, non-porous surfaces, equipment, utensils and instruments in equine veterinary practices and stables.

USES: Barn Aisles, Stables, Box Stalls, Tack, Equipment, Transport Vehicles and Trailers and Feed Rooms: Follow general instructions to remove animals from area to be treated. Thoroughly clean or dry clean surfaces, then wash the area manually or with pressure washer with a 1% BioBuster solution, saturating surfaces for a period of 10 minutes. Allow surfaces to air dry. Rinse waterers and feeders with potable water before reuse.]

[BOVINE PRODUCTION]:

[Follow General Instructions to remove livestock and pre-clean the area to be treated. Use a 1% solution of BioBuster to disinfect areas associated with bovine housing, hospital quarantine pens, feedlot facilities, and agricultural production equipment: such as trucks, rubber boots and

associated livestock equipment and instruments. Saturate surfaces with a 1% solution of BioBuster with a cloth, mop, mechanical spray, or sponge and allow to sit for a period of 10 minutes. Allow surfaces to air dry. Rinse waterers and feeders with potable water before reuse.]

~~[Fogging (Wet Misting) – Bovine~~

~~Follow General Instructions to remove animals from room to be treated.~~

~~Use a 0.5% - 1.0% solution of BioBuster for fogging (wet misting) operations as a supplemental measure after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions. Rinse foggers and sprayers with potable water following use. Refer to Fogging (Wet Misting instructions)].~~

[COMPANION ANIMALS]:

[APPLICATIONS: Use a 1% solution of BioBuster as a "one step" cleaning and disinfecting procedure (Remove gross filth and heavy soil deposits before application of the disinfecting/cleaning solution) for all surfaces, equipment, instruments, utensils and cages within Veterinary Medical Hospitals, quarantine areas, laboratory animal quarters, grooming and boarding facilities, kennels, catteries and animal transportation vehicles. Saturate surfaces with a 1% solution of BioBuster with a cloth, mop, spray, or sponge and allow to remain for a period of 10 minutes. Allow surfaces to air dry. Rinse waterers and feeders with potable water before reuse.

Do not immerse metal objects for long periods - 10 minutes is maximum contact time.]

[GREENHOUSES AND HORTICULTURE]:

[BioBuster is intended to disinfect inanimate environmental surfaces: such as floors, walls, glass greenhouse structures, ventilation equipment, utensils, trays, containers, water systems, evaporative coolers, storage rooms, and vehicles in greenhouses and other horticultural settings prior to introduction or reintroduction of plants, seeds, or soil. Must not be applied to plants, seeds, or soil. If necessary, remove or cover these items prior to use of the product.]

[For surfaces and equipment including pots, flats, trays, pruning equipment, carts and transport vehicles]:
Sweep and remove all plant debris. Use a high pressure washer to wash all surfaces to remove loose dirt. Use a dilution of 1:100 (1.3 oz powder concentrate added to 1 gallon of water). Use a dilution of 1:50 or 2.6 oz. BioBuster per gallon of clean water if surfaces to be treated have not been pre-cleaned. Apply the solution with a mop, sponge, or power sprayer, ~~or fogger~~ to thoroughly wet all surfaces. Heavy growth of algae or fungi may have to be scrubbed off following application.

[For evaporative coolers: Treat existing algae and slime contaminated surfaces with a 1:100 dilution of BioBuster. Cooler water should be treated weekly with a dilution of 1:200.]

[BioBuster may also be used to disinfect irrigation tanks and lines. Create a 1% stock solution. Run the 1% solution through the system or soak equipment in a 1% solution. Let stand for ten minutes and then flush the system with clean water.

~~[Fogging (Wet Misting) Instructions – Greenhouse/Horticulture]~~

~~[Use a 0.5% - 1.0% solution of BioBuster for fogging (wet misting) operations as a supplemental measure after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions. Rinse foggers and sprayers with potable water following use. Refer to Fogging (Wet Misting instructions)].~~

[AQUACULTURE]:

[BioBuster is intended to disinfect inanimate environmental surfaces associated with aquaculture production including vehicles, dip nets, boots, waders, hoses, brushes and other similar equipment. BioBuster must not be applied directly to water.]

]

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal. **STORAGE:** Store in a cool dry place in tightly closed container. Keep out of reach of children. Always replace lid after use. **PESTICIDE DISPOSAL:** Pesticide wastes may be hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance. **CONTAINER DISPOSAL: Nonrefillable container. Do not reuse or refill this container.** Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

Decision #: 551035
DP #: (453013)
PRIA
Parent DP #:
Submission #: 1034761
E-Sub #: 39226

DATA PACKAGE BEAN SHEET

Date: 28-Jun-2019

* * * Registration Information * * *

Registration: 92589-R - BioBuster

Company: 92589 - ENVYSS, LLC

Risk Manager: RM 34 - Jacqueline Hardy - 703-308-6416 Room# PY1 S-8317

Risk Manager Reviewer: Lorena Rivas LRIVAS

Sent Date: PRIA Due Date: 06-Nov-2019 Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (A540) New end use product;FIFRA §2(mm) uses only;up to 25 public health organisms;

Ingredients: 013905, Sodium chloride(1.5%)

063604, Potassium peroxymonosulfate(21.41%)

* * * Data Package Information * * *

Expedite: ● Yes ○ No Date Sent: 28-Jun-2019 Due Back:

DP Ingredient: 013905, Sodium chloride

063604, Potassium peroxymonosulfate

DP Title: Product Chemistry

CSF Included: ● Yes ○ No Label Included: ● Yes ○ No Parent DP #:

Assigned To	Data In	Date Out	
Organization: AD / PSB		7/2	Last Possible Science Due Date: 07-Oct-2019
Team Name: CTT		7/2	Science Due Date:
Reviewer Name: Lynett Contractor		7/3	Sub Data Package Due Date:
Contractor Name:			

* * * Studies Sent for Review * * *

Printed on Page 2

* * * Additional Data Package for this Decision * * *

No Additional Data Packages

* * * Data Package Instructions * * *

PRIA: New hospital Disinfectant
Electronic Submission - Pls go to Documentum for Info

Science Technical Screen Due Date: August 1, 2019
Please review the basic CSF and product chem data in MRID 50847901-50847902 for completeness

Data Evaluation
Please review the data and CSF to determine if its acceptable to support this product's registration

Sent email to K. Hicks, J. Campbell, Lorena Rivas on 9/4/2019 technical screen passed.

DP#: (453013) *** Studies Sent for Review *** Decision#: (551035)

50847901	Toxcel, LLC (2019) BioBuster: Group A Product Chemistry. Unpublished study prepared by ToXcel, LLC. 154p.	830.1550/Product identity and composition	Not Reviewed (14-May-2019)
50847901	Toxcel, LLC (2019) BioBuster: Group A Product Chemistry. Unpublished study prepared by ToXcel, LLC. 154p.	830.1600/Description of materials used to produce the product	Not Reviewed (14-May-2019)
50847901	Toxcel, LLC (2019) BioBuster: Group A Product Chemistry. Unpublished study prepared by ToXcel, LLC. 154p.	830.1620/Description of production process	Not Reviewed (14-May-2019)
50847901	Toxcel, LLC (2019) BioBuster: Group A Product Chemistry. Unpublished study prepared by ToXcel, LLC. 154p.	830.1650/Description of formulation process	Not Reviewed (14-May-2019)
50847901	Toxcel, LLC (2019) BioBuster: Group A Product Chemistry. Unpublished study prepared by ToXcel, LLC. 154p.	830.1670/Discussion of formation of impurities	Not Reviewed (14-May-2019)
50847901	Toxcel, LLC (2019) BioBuster: Group A Product Chemistry. Unpublished study prepared by ToXcel, LLC. 154p.	830.1700/Preliminary analysis	Not Reviewed (14-May-2019)
50847901	Toxcel, LLC (2019) BioBuster: Group A Product Chemistry. Unpublished study prepared by ToXcel, LLC. 154p.	830.1750/Certified limits	Not Reviewed (14-May-2019)
50847901	Toxcel, LLC (2019) BioBuster: Group A Product Chemistry. Unpublished study prepared by ToXcel, LLC. 154p.	830.1800/Enforcement analytical method	Not Reviewed (14-May-2019)
50847902	Toxcel, LLC (2019) BioBuster: Group B Product Chemistry. Unpublished study prepared by Envyss, LLC. 24p.	830.6302/Color	Not Reviewed (14-May-2019)
50847902	Toxcel, LLC (2019) BioBuster: Group B Product Chemistry. Unpublished study prepared by Envyss, LLC. 24p.	830.6303/Physical state	Not Reviewed (14-May-2019)
50847902	Toxcel, LLC (2019) BioBuster: Group B Product Chemistry. Unpublished study prepared by Envyss, LLC. 24p.	830.6304/Odor	Not Reviewed (14-May-2019)
50847902	Toxcel, LLC (2019) BioBuster: Group B Product Chemistry. Unpublished study prepared by Envyss, LLC. 24p.	830.6313/Stability to normal and elevated temperatures, metals, and metal ions	Not Reviewed (14-May-2019)
50847902	Toxcel, LLC (2019) BioBuster: Group B Product Chemistry. Unpublished study prepared by Envyss, LLC. 24p.	830.6314/Oxidizing or reducing action	Not Reviewed (14-May-2019)
50847902	Toxcel, LLC (2019) BioBuster: Group B Product Chemistry. Unpublished study prepared by Envyss, LLC. 24p.	830.6315/Flammability	Not Reviewed (14-May-2019)
50847902	Toxcel, LLC (2019) BioBuster: Group B Product Chemistry. Unpublished study prepared by Envyss, LLC. 24p.	830.6316/Explodability	Not Reviewed (14-May-2019)
50847902	Toxcel, LLC (2019) BioBuster: Group B Product Chemistry. Unpublished study prepared by Envyss, LLC. 24p.	830.6317/Storage stability	Not Reviewed (14-May-2019)
50847902	Toxcel, LLC (2019) BioBuster: Group B Product Chemistry. Unpublished study prepared by Envyss, LLC. 24p.	830.6319/Miscibility	Not Reviewed (14-May-2019)
50847902	Toxcel, LLC (2019) BioBuster: Group B Product Chemistry. Unpublished study prepared by Envyss, LLC. 24p.	830.6320/Corrosion characteristics	Not Reviewed (14-May-2019)
50847902	Toxcel, LLC (2019) BioBuster: Group B Product Chemistry. Unpublished study prepared by Envyss, LLC. 24p.	830.6321/Dielectric breakdown voltage	Not Reviewed (14-May-2019)
50847902	Toxcel, LLC (2019) BioBuster: Group B Product Chemistry. Unpublished study prepared by Envyss, LLC. 24p.	830.7000/pH	Not Reviewed (14-May-2019)
50847902	Toxcel, LLC (2019) BioBuster: Group B Product Chemistry. Unpublished study prepared by Envyss, LLC. 24p.	830.7100/Viscosity	Not Reviewed (14-May-2019)
50847902	Toxcel, LLC (2019) BioBuster: Group B Product Chemistry. Unpublished study prepared by Envyss, LLC. 24p.	830.7200/Melting point/melting renge	Not Reviewed (14-May-2019)

DP#: (453013) *** Studies Sent for Review *** Decision#: (551035)

50847902		Toxcel, LLC (2019) BioBuster: Group B Product Chemistry. Unpublished study prepared by Envyss, LLC. 24p.	830.7220/Boiling point/boiling range	Not Reviewed (14-May-2019)
50847902		Toxcel, LLC (2019) BioBuster: Group B Product Chemistry. Unpublished study prepared by Envyss, LLC. 24p.	830.7300/Density/relative density	Not Reviewed (14-May-2019)
50847902		Toxcel, LLC (2019) BioBuster: Group B Product Chemistry. Unpublished study prepared by Envyss, LLC. 24p.	830.7370/Dissociation constants in water	Not Reviewed (14-May-2019)
50847902		Toxcel, LLC (2019) BioBuster: Group B Product Chemistry. Unpublished study prepared by Envyss, LLC. 24p.	830.7550/Partition coefficient (n-octanol/water), shake flask method	Not Reviewed (14-May-2019)
50847902		Toxcel, LLC (2019) BioBuster: Group B Product Chemistry. Unpublished study prepared by Envyss, LLC. 24p.	830.7840/Water solubility: Column elution method, shake flask method	Not Reviewed (14-May-2019)
50847902		Toxcel, LLC (2019) BioBuster: Group B Product Chemistry. Unpublished study prepared by Envyss, LLC. 24p.	830.7950/Vapor pressure	Not Reviewed (14-May-2019)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

Office of Pesticide Programs

MEMORANDUM

11/1/2019

SUBJECT: Product Chemistry Review for **BioBuster** EPA Reg. No.: **92589-R**

FROM: Lynette T. Umez-Eronini
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

THRU: Karen P. Hicks, Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

TO: Jacqueline Hardy, PM Team 34 / Lorena Rivas
Regulatory Management Branch II
Antimicrobials Division (7510P)

Registrant: Envyss LLC
Action code: A540
Agency Due Date: 11/6/2019
DP No.: 453013
Submission No.: 1034761
E-Sub No.: 39226
Classification: EP
Process: Integrated system
Pesticide type: Antimicrobial

MRID(s):50847901, 50847902

Formulation from label			
PC code(s)	CAS #(s)	Active Ingredient(s)	% weight
063604	10058-23-8	Potassium peroxymonosulfate	21.40
013905	7647-14-5	Sodium chloride	1.50
		Other Ingredients	77.10
		Total	100.00

I. BACKGROUND

The Registrant, Envyss LLC, has submitted an application for pesticide registration for their product: BioBuster EPA Reg. No. 92589-R.

II. RELEVANT DOCUMENTS

	RECEIVED	N/A
EPA FORM 8570-1 Application for Pesticide Registration (5/13/2019)	☒	☐
EPA FORM 8570-27 – Formulator's Exemption Statement	☐	☒
EPA FORM 8570-34 – Certification with Respect to Citation of Data (5/13/2019)	☒	☐
EPA FORM 8570-35 – Data Matrix (5/13/2019)	☒	☐
Cover letter (5/19/2019)	☒	☐
Transmittal document (5/13/2019)	☒	☐
Proposed CSF BASIC and ALTERNATE 1, (11/1/2019)	☒	☐
Proposed label, 10/28/2019	☒	☐
Registrant's letter, Ref. BVBV/2019-20/ dated (10/29/2019)	☒	☐
	☐	☐
REFERENCED: CSF	--	
Comments:		

III. FINDINGS

a. Product Formulation:

	TGAI	MUP	EUP	Food use	Non-food use
Non-integrated	☐	☐	☐	☐	☐
Integrated	☐	☐	☒	☐	☒

Active Ingredients(s)	Nominal	Upper limit	Lower limit
Potassium peroxymonosulfate	21.4	22.0	20.8
Sodium chloride	1.5	1.56	1.41
	YES	**NO**	**N/A**
1. The certified limits of all ingredients are within 40 CFR standard certified limits.	☒	☐	☐
2. Wider certified limits were requested and rationale was accepted.	☐	☐	☒
3. The nominal concentration(s) of the active ingredient is in agreement with the label.	☒	☐	☐

4. The chemical IDs and analytical information for density, pH, and flammability are consistent with Series 830 Group B data.	☒	☐	
5. All inert ingredients are approved for non-food use pesticide formulations.	☒	☐	☐
6. The impurities present >0.1% are identified.	☐	☐	☒
7. Impurities of toxicological significance have an upper certified limit.	☐	☐	☒

b. Product Label:

	Yes	NO	N/A
The formula contains one of the following:			
1. 10% or more of petroleum distillate	☐	☒	☐
2. 1.0% or more of methyl alcohol	☐	☒	☐
3. Sodium nitrite at any level	☐	☒	☐
4. A toxic list 1 inert at any level	☐	☒	☐
5. Arsenic in any form	☐	☒	☐
6. If yes to 1-5, then the inert ingredient list contains a relevant footnote	☐	☐	☒
7. Appropriate warning statements regarding flammability or explosive characteristics of the product are included on the label	☐	☐	☒
8. The storage and disposal instructions for the pesticide container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses.	☒	☐	☐
9. The product requires an expiration date at which time the nominal concentration falls below the lower certified limit.	☐	☐	☒

IV. Additional Findings

1. Basic and Alternate 1 CSFs dated 11/1/2019 are acceptable.
2. Group A product chemistry data requirements applicable to end-use product have been met (see MRID 50847901 on Table A below).
3. Group B product chemistry data requirements applicable to end-use product have been met (see MRID 50847902 on Table B below).
   Note: The 830.6317 Storage Stability and 830.6320 Corrosion Characteristics studies were conducted at 3, 6, 9, 12, 15, 18, and 24 months and 30°C ± 2°C (MRID 50847902). The concentrations of active ingredients were found to lie within EPA Standard certified limits over the duration of the studies. Registrant's letter dated 10/29/2019 confirmed that the product is compatible with its HDPE container and does not corrode the container for the duration of and 3 months beyond the expiry date (same as 24 months study period).

V. Conclusion

The Product Science Branch of Antimicrobials Division finds Group A and B Product Chemistry Data requirements have been met. Basic and Alternate 1 CSFs dated 11/1/2019 are acceptable.

VI. Table A:
Series 830 guidelines – Group A

OPPTS#	Name	Status	MRID
830.1550	Product Identity & Composition	Acceptable	50847901
830.1600	Description of materials	Acceptable	50847901
830.1620	Description of production process	Acceptable	50847901
830.1650	Description of formulation process	Acceptable	50847901
830.1670	Discussion of formation of impurities	Acceptable	50847901
830.1700	Preliminary analysis	Acceptable	50847901
830.1750	Certified limits	Requires upgrading	CSF, dated 10/31/2019
830.1800	Enforcement analytical method	Acceptable	50847901
830.1900	Submittal of samples	Acceptable	50847901 S0472810

VII. Table B: Series 830 guidelines – Group B

OPPTS#	Name	Study Findings/Comment	Status	MRID
830.6302	Color	Not required for end use product	Not applicable	N/A
830.6303	Physical state	solid	Acceptable	50847902
830.6304	Odor	Not required for end use product. Registrant reported a lemon perfume scent.	Not applicable	N/A 50847902
830.6313	Stability to normal & elevated temperatures, metals & metal ions	The product is not TGAI	Not applicable	N/A
830.6314	Oxidation/Reduction	BioBuster is an oxidizer.	Acceptable	50847902
830.6315	Flammability	N/A. The product does not contain combustible liquids.	Acceptable	50847902
830.6316	Explodability	N/A. The product is not potentially explosive and does not possess any explosive properties.	Acceptable	50847902
830.6317	Storage stability	The concentrations of active ingredients were found to lie within EPA Standard certified limits over the duration of the studies.	Acceptable	50847902
830.6319	Miscibility	N/A. The product is not an emulsifiable liquid and will not be diluted with petroleum solvents.	Acceptable	50847902
830.6320	Corrosion characteristics	The product is compatible with HDPE container and does not corrode the container for the duration and 3 months beyond the expiry date (same as 24 months study period).	Acceptable	50847902 & Registrant's letter, dated 10/29/2019
830.6321	Dielectric breakdown voltage	N/A. Product is not a liquid to be used around electrical equipment.	Acceptable	50847902
830.7000	pH	2.10 -2.S0	Acceptable	50847902
830.7050	UV/Visible absorption	Not required for MUP or EP	Not applicable	N/A
830.7100	Viscosity	N/A. The product is not a liquid.	Acceptable	50847902

830.7200	Melting point	Not required for MUP or EP	Not applicable	N/A
830.7220	Boiling point	Not required for MUP or EP	Not applicable	N/A
830.7300	Density/relative	1.15 – 1.30 g/cm^3	Acceptable	50847302
830.7370	Dissociation constants in water	Not required for MUP or EP	Not applicable	N/A
830.7520	Particle size	Not required for MUP or EP	Not applicable	N/A
830.7550/ 7560/ 7570	Partition coefficient	Not required for MUP or EP	Not applicable	N/A
830.7840/ 7860	Water solubility	Not required for MUP or EP	Not applicable	N/A
830.7950	Vapor pressure	Not required for MUP or EP	Not applicable	N/A

CONFIDENTIAL ATTACHMENT

Pages 24-27 Confidential Statement of Formula may be entitled to confidential treatment

From: Nelson Cornwell
To: Eronini, Lynette
Cc: Connie Welch-DuJardin; Melba Morrow; Alan Katz
Subject: RE: 92589-R_D453013_BioBuster
Date: Tuesday, October 29, 2019 8:56:33 AM
Attachments: 830.6320 Corrosion Characteristics for BioBuster.pdf

Good Morning Lynette,

I apologize for the delay.

Please find attached the Corrosion Characteristics for BioBuster.

Best regards,
Nelson

From: Nelson Cornwell
Sent: Monday, October 28, 2019 4:51 PM
To: Eronini, Lynette <Eronini.Lynette@epa.gov>
Cc: Connie Welch-DuJardin <Connie.Welch-DuJardin@toxcel.com>; Melba Morrow <Melba.Morrow@toxcel.com>; Alan Katz <Alan.Katz@toxcel.com>
Subject: RE: 92589-R_D453013_BioBuster

Hi Lynette,

I hope this finds you well.

I have attached the updated label (track changes and clean), CSFs, and Oxidation/Reduction.

We are still awaiting a response concerning Corrosion Characteristics. The lab that was used is located in India and with the time difference and the holiday (Festival of Lights is what I'm being told) there has been a delay. We are hopeful we can get a statement from them in the morning.

The CSFs are password protected. I will send the password in a separate email.

Please let us know what else you may need from us.

Best regards,
Nelson

From: Eronini, Lynette [mailto:Eronini.Lynette@epa.gov]
Sent: Tuesday, October 22, 2019 11:25 AM
To: Alan Katz <Alan.Katz@toxcel.com>
Cc: Melba Morrow <Melba.Morrow@toxcel.com>; Rivas, Lorena <Rivas.Lorena@epa.gov>; Hardy, Jacqueline <Hardy.Jacqueline@epa.gov>
Subject: RE: 92589-R_D453013_BioBuster

Alan and Melba,
Thanks for making it possible to have a conference call with no internet and telephonic connection at your agency. If there are questions concerning the issues that were discussed, please contact me. I look to receive updated/corrected documents between Friday, October 25, 2019 and Monday, October 28, 2019.

Lynette T. Umez-Eronini
Antimicrobials Division
Office of Pesticide Program
703-347-0132

From: Eronini, Lynette
Sent: Monday, October 21, 2019 3:46 PM
To: Alan Katz <Alan.Katz@toxcel.com>
Subject: RE: 92589-R_D453013_BioBuster

Great!
Lynette

From: Alan Katz <Alan.Katz@toxcel.com>
Sent: Monday, October 21, 2019 3:33 PM
To: Eronini, Lynette <Eronini.Lynette@epa.gov>
Cc: Melba Morrow <Melba.Morrow@toxcel.com>; Hardy, Jacqueline <Hardy.Jacqueline@epa.gov>; Rivas, Lorena <Rivas.Lorena@epa.gov>; Nelson Cornwell <Nelson.Cornwell@toxcel.com>
Subject: RE: 92589-R_D453013_BioBuster

Lynette,

Thanks for your email message. We will call you between 10:00-10:30 AM tomorrow to discuss the issues that you mentioned.

Kind regards,
Alan

Alan C. Katz
PRESIDENT

toXcel LLC
7140 Heritage Village Plaza
Gainesville, VA 20155
USA
Ph (USA): +1 (703) 754-0248 ext. 8111
Ph (UK link): +44 (0) 20 7993 6957
Fax: +1 (703) 310-6950

www.toxcel.com

From: Eronini, Lynette [mailto:Eronini.Lynette@epa.gov]
Sent: Monday, October 21, 2019 3:11 PM
To: Alan Katz <Alan.Katz@toxcel.com>
Cc: Melba Morrow <Melba.Morrow@toxcel.com>; Hardy, Jacqueline <Hardy.Jacqueline@epa.gov>; Rivas, Lorena <Rivas.Lorena@epa.gov>
Subject: 92589-R_D453013_BioBuster

Alan Katz,
Thanks for returning my call. Please set up conference call with Melba Morrow, you and me and call me between 10 and 10:45 AM. on Tuesday, October 22, 2019 to discuss issues that are mentioned in the attachment.

Lynette T. Umez-Eronini
Antimicrobials Division
Office of Pesticide Program
703-347-0132

B.V. BIO-CORP. PVT. LTD.

(An ISO 9001 : 2015 & GMP Certified Company)

Ref. BVBV/2019-20/
Date: 29.10.2019

To Whom it may concern

Certified that we at B.V. Bio-Corp Pvt. Ltd, are packing the product Bio-Buster in HDPE containers. On long time storage study, 3 months beyond expiry date, we found no corrosion occurred to HDPE container. We confirm that the product is compatible with HDPE material and doesn't corrode the containers.

For **B.V. Bio-Corp Pvt. Ltd.**

Dy. General Manager
Authorized Signatory

Works: Village Patvi, P.O.Jatwar, Tehsil Naraingarh, Distt. Ambala, Haryana (India) -134 201.
Phone : 01734-271161, 271488, Fax : 01734-271162 E-mail : chd.ahpsite@venkys.com
Corporate : "Venkateshwara House", S.No. 114/A/2, Pune-Sinhagad Road, Pune-411 030 .
Phone : 020-24251530 - 1541 Fax : 020-24251077, 24251060
CIN No. U15332PN2002PTC016680

Rivas, Lorena

From: Nelson Cornwell <Nelson.Cornwell@toxcel.com>
Sent: Wednesday, November 06, 2019 3:23 PM
To: Rivas, Lorena; Melba Morrow
Cc: OPP AD Ombudsman; Montague, Kathryn V.
Subject: RE: Completed action for conditional Registration Notice No. 92589-1

Hi Lorena,

This is great news.

I have received the attachment.

Thanks for your help.

Best regards,
Nelson

From: Rivas, Lorena [mailto:Rivas.Lorena@epa.gov]
Sent: Wednesday, November 6, 2019 1:51 PM
To: Nelson Cornwell <Nelson.Cornwell@toxcel.com>; Melba Morrow <Melba.Morrow@toxcel.com>
Cc: OPP AD Ombudsman <OPP_AD_Ombudsman@epa.gov>; Montague, Kathryn V. <Montague.Kathryn@epa.gov>
Subject: Completed action for conditional Registration Notice No. 92589-1

Hello Nelson,

Enclosed you will find the Acceptable Conditional Registration for Decision No. 551035 , for product: 8ioBuster.
In addition you will find a copy of the stamped label dated 11/06/2019..
Do not hesitate to email me with any additional questions.
Please reply with an email that you received all the attachments.

Regards

Lorena Rivas
Registration Risk Manager
Antimicrobials Division (AD)
Environmental Protection Agency
2777 South crystal Drive
Arlington, VA 22202
Rivas.lorena@epa.gov

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Antimicrobials Division (7510P)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

NOTICE OF PESTICIDE:
_X_ Registration
___ Reregistration
(under FIFRA, as amended)

EPA Reg. Number:	Date of Issuance:
92589-1	11/06/2019

Term of Issuance:
Conditional

Name of Pesticide Product:
BioBuster

Name and Address of Registrant (Include ZIP Code):

Envyss, LLC
P.O. Box 907
Blue Ridge, GA 30513

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Antimicrobials Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Jacqueline Hardy

Jacqueline Hardy, Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510P)

Date: 11/06/2019

2. You are required to comply with the data requirements described in the DCI or EDSP identified below:
    a. Potassium peroxymonosulfate GDCI-063201-1126
    b. Sodium chloride GDCI-013907-1169

    You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI listed above, you may contact the Reevaluation Team Leader (Team 36): http://www2.epa.gov/pesticide-contacts/contacts-office-pesticide-programs-antimicrobial-division

3. Be aware that proposed data requirements for Potassium peroxymonosulfate, and Sodium chloride have been identified in a Work Plan. For more information on these proposed data requirements, you may obtain copies in the docket EPA-HQ-OPP-2009-0546 and EPA-HQ-OPP-2009-0168 at www.regulations.gov or contact the contact the Reevaluation Team Leader (Team 36): http://www2.epa.gov/pesticide-contacts/contacts-office-pesticide-programs-antimicrobial-division

4. Make the following label changes before you release the product for shipment:

    - Revise the EPA Registration Number to read, "EPA Reg. No. 92589-1."

5. Submit one copy of the final printed label for the record before you release the product for shipment.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records.

Please also note that the record for this product currently contains the following CSFs:

- Basic Formulation CSF dated 11/01/2019
- Alternate Formulation 1 dated 11/01/2019

In addition; the following seven alternate brand names has been added to the product record:

- BioBuster Disinfectant and Virucide
- BioBuster Broad Spectrum Disinfectant
- BioBuster VC Broad Spectrum Disinfectant for Veterinary Clinic Use
- BioBuster VC Disinfectant and Virucide for Veterinary Clinic Use
- BioBuster HD Disinfectant and Virucide for Farm Use
- BioBuster Greenhouse Disinfectant and Virucide
- BioBuster FP Broad Spectrum Hard Non-porous Disinfectant for Animal Processing Facilities

If you have any questions, please contact Lorena Rivas by phone at (703) 305-5027, or via email at rivas.lorena@epa.gov.

Enclose: Stamped Label

All text in brackets [ ] is optional and may or may not be included on ... final label.

BioBuster
Broad Spectrum Disinfectant and Virucide
Deodorizer

Alternate Brand Names
BioBuster Disinfectant and Virucide

BioBuster Broad Spectrum Disinfectant
BioBuster VC Broad Spectrum Disinfectant for Veterinary Clinic Use
BioBuster VC Disinfectant and Virucide for Veterinary Clinic Use
BioBuster HD Disinfectant and Virucide for Farm Use
BioBuster Greenhouse Disinfectant and Virucide
BioBuster FP Broad Spectrum Hard Non-porous Disinfectant for Animal Processing Facilities

[BROAD SPECTRUM DISINFECTANT for Hard Non-Porous Surfaces,] [CLEANER,] [VIRUCIDE,] [& ALGAECIDE]. [Poultry Hatchery Disinfectant] [Farm Premise Disinfectant] [Veterinary and Animal Hospital Disinfectant] [For Poultry, Swine and Livestock Premises] [For Veterinary, Laboratory Animal, Kennel and Animal Breeder Facilities] [Effective in 400ppm Hard Water as CaCO3] [Disinfects in 5% Organic Soil Load] [For Greenhouse Facilities and Equipment] [For use in Horticulture] [Processing and Slaughter Plant Disinfectant] [For Aquaculture Facilities] [Routine Cleaning in Commercial and Industrial Facilities]

For Use in Cleaning or Disinfecting Industrial, Commercial, Animal and Agricultural Facilities. BioBuster can also be used as a deodorizer.

Effective against:
Virus
Bacteria

ACTIVE INGREDIENTS:	
Potassium peroxymonosulfate	21.40%
Sodium Chloride	1.50%
OTHER INGREDIENTS	77.10%
TOTAL	100.00%

KEEP OUT OF REACH OF CHILDREN
DANGER/PELIGRO

EPA Reg. No. 92589-1
EPA Est. No.
Batch No:
Expiry Date:
Net Contents:

All text in brackets [ ] is optional and may or may not be included on a final label.

FIRST AID	
If in Eyes:	Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after 5 minutes, then continue rinsing eye. Call a Poison Control Center or doctor for further treatment advice.
If on Skin or Clothing:	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a Poison Control Center or doctor for further treatment advice.
If Swallowed:	Call a Poison Control Center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor Do not give anything by mouth to an unconscious person
FOR EMERGENCY INFORMATION	
[For 24-hour emergency information on this product, call the poison control center 1-800-222-1222.] Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	
Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.	

Manufactured for:
EnVyss, LLC
178 Rowland Pointe
Morganton, GA 30560

All text in brackets [ ] is optional and may or may not be included on ... inal label.

BioBuster is effective against:

BACTERIA:

[Aeromonas hydrophila (ATCC19570)]
[Campylobacter jejuni (ATCC 33560)]
[Escherichia coliO157:H7 (ATCC 35150)]
[Haemophilus somnus (ATCC 700026)]
[Mycoplasma gallisepticum (ATCC15302)]
[Pectobacterium carotovorum (ATCC15713)]
[Pseudomonas aeruginosa (ATCC15442)]
[Salmonella enterica (ATCC10708)]
[Staphylococcus aureus (ATCC6538)]
[Streptococcus suis (ATCC 43765)]
[Bordetella avium ATCC35086)]
[Bordatella bronchioseptica (ATCC10580)]
[Listeria monocytogenes (ATCC984)]
[Streptococcus pneumoniae (ATCC 33400)]
[Xanthomonas campestris (ATCC 11058)]

VIRUSES:

Avian Influenza Virus (H5N1) (Strain VNH5N1-PR8/CDC-RG)

Bovine Adenovirus Type 4
Bovine Polyoma Virus
Bovine Pseudocowpox Virus
Bovine Viral Diarrhea Virus (Strain : NADL (America Bioresearch laboratories)
Calf Rotavirus (no hard water –dilute with deionized water)
Canine Adenovirus (Canine Hepatitis)
Canine Corona Virus
Canine Parainfluenza Virus
Canine Parvovirus(Strain:Cornell-780916-80, ATCC VR-2017)
Chicken Anemia Virus
Coital Exanthema Virus
Distemper Virus
Duck Adenovirus (no hard water –dilute with deionized water)
Duck Enteritis Virus
Egg Drop Syndrome Virus

Equine Herpes Virus (Type3)
Equine Influenza Virus (Type A)
Equine papilloma virus

Feline Herpes Virus

All text in brackets [ ] is optional and may or may not be included on final label.

Feline Infectious Peritonitis Virus (Strain FIPV-1146, P100 ATCC VR-2202)
Feline Panleukopenia Virus
Hog Cholera Virus
Infectious Laryngeotracheitis Virus (Strain LT-IVAX)
Infectious Pancreatic Necrosis
Infectious Salmon Anemia Virus
Marek's Disease
Mouse Parvovirus
Pigeon Adenovirus (Strain IDA4: RVB-0146)
Porcine Parvovirus

Snakehead Rhabdovirus
Swine Influenza Virus
Swine Vesicular Stomatitis Virus
Turkey Herpes Virus (no hard water- dilute with deionized water)
Vesicular Stomatitis Virus

[PLANT PATHOGENS]
[Botrytis cinera]
[Fusarium oxysporum]
[Penicillium oxalicum]
[Pythium aphanidermatium]
[Rhizoctonia solani]
[Sclerotinia sclerotiorum]

PRECAUTIONARY STATEMENTS:
Hazards to human and domestic animals.
DANGER. Powder is corrosive in concentrated form.
Causes irreversible eye damage or skin burns. Harmful if swallowed or absorbed through the skin. Do not get in eyes, on skin or on clothing. Wear protective eyewear, protective clothing and rubber gloves. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.
Corrosive statement refers to powder only and not to the product in use dilution.

ENVIRONMENTAL HAZARDS:

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

All text in brackets [ ] is optional and may or may not be included on final label.

[BioBuster Virucide and Disinfectant is a complete, chemically balanced disinfectant formulated to be environmentally friendly. BioBuster Virucide and Disinfectant provides broad spectrum efficacy, killing gram positive and gram negative bacteria, virus, mycoplasma [and inhibiting the formation of slime and algae and associated slime forming bacteria] in industrial, animal and agricultural facilities and for use in greenhouses, borticulture and aquaculture on bard non-porous surfaces.

DIRECTIONS FOR USE
It is a violation of Federal law to use this product in a manner inconsistent with its labeling

GENERAL INSTRUCTIONS — FARM PREMISES, ANIMAL HOUSING BUILDINGS AND FARM EQUIPMENT

1. Remove all animals and feed from premises, vehicles and enclosures. Remove all litter and manure from floors, walls and surfaces of barns, pens, stalls, chutes and other facilities and fixtures occupied or traversed by animals. Empty all troughs, racks, and other feeding and watering appliances.

2. Thoroughly clean all surfaces with detergent and rinse with water.

3. Saturate all surfaces with the appropriate disinfection solution. Surfaces must remain wet for 10 minutes.

4. Immerse all animal handling equipment and forks, shovels, and scrapers used for removing litter and manure in the appropriate disinfection solution for 10 minutes. Allow to air dry.

5. Ventilate buildings and other closed spaces. Do not house animals or livestock or use equipment until the disinfection solution has been absorbed, set, or dried.

6. Thoroughly scrub treated feed racks, troughs, automatic feeders, and waterers with detergent and rinse with potable water before reuse.

BIOBUSTER MIXING INSTRUCTIONS:
To mix the appropriate use-diluted solution of BioBuster, first identify the percent solution desired. Second, fill a clean container with the volume of water for the desired percent solution and then add the associated quantity of powder (using the provided scoop) found in the following table. One scoop (1.3 ounces of powder) added to one gallon of water will yield a 1% solution.

Quantity of Water	0.5% Solution	1% Solution	2% Solution
1 Quart	0.15 ounces	0.325 ounces	0.7 ounces
1 Gallon	0.65 ounces	1.3 ounces	2.7 ounces
10 Gallons	6.7 ounces	13.4 ounces	26.7 ounces
50 Gallons	33.4 ounces	66.8 ounces	133.5 ounces

All text in brackets [ ] is optional and may or may not be included on the final label.

10 minutes is maximum necessary contact time. One gallon of solution is sufficient to treat 135 sq. ft.

[WATER SYSTEM TANK DISINFECTANT]:

Application	Dilution Rate	Instructions
Terminal Disinfection	1:100	Isolate the header tank at the main. Drain the line. Clean out gross soiling and debris. Refill with water and add the appropriate volume of BioBuster, mix well and let sit for 10 minutes. Flush the system to all drain off points and let sit for another 50 minutes. Drain the system and refill with clean water.
Continuous disinfection	1:100	Dose the header tank as required or apply through water system dosing equipment.

[BOOT DIPS]:

[Use a 1% solution in boot baths for the routine disinfection of footwear. Replace the solution daily or more often if the solution becomes visibly soiled.]

[POULTRY PRODUCTION]:

[HATCHERIES: BioBuster at 1% solution can be used for cleaning and disinfecting hatchers, setters, evaporative coolers, humidifying systems, transfer trucks, trays, racks, carts, sexing tables and plastic chick boxes. Saturate surfaces with a 1% solution with a coarse spray, cloth, mop or sponge and let sit for a period of 10 minutes. Allow surfaces to air dry.]

[BROILER/BREEDER HOUSES: Follow General Instructions to remove poultry and clean the area to be treated. Spray floors and walls with BioBuster at 1% solution. Thoroughly wash waterers and feeders with a 1% solution of BioBuster. After contact for 10 minutes, rinse with potable water. Do not house poultry or use equipment until treatment has dried.]

[PROCESSING PLANTS: Spray BioBuster at 1% solution to disinfect and clean walls, ceilings and floors. Saturate surfaces for a period of 10 minutes. Allow surfaces to air dry.

All text in brackets [ ] is optional and may or may not be included on final label.

[SWINE PRODUCTION]:

[Follow General Instructions to remove swine and clean the area to be disinfected. Use a 1% solution of BioBuster for cleaning and disinfecting farrowing units, nurseries, finisher houses, processing plants, and agricultural production equipment such as trucks, rubber boots and associated livestock equipment. Saturate surfaces with a 1% solution with a cloth, mop, mechanical spray or sponge for a period of 10 minutes. Allow surfaces to air dry. Rinse waterers and feeders with potable water before reuse.]

[EQUINE FACILITIES]:

[APPLICATIONS: For cleaning and disinfecting all hard, non-porous surfaces, equipment, utensils and instruments in equine veterinary practices and stables.

USES: Barn Aisles, Stables, Box Stalls, Tack, Equipment, Transport Vehicles and Trailers and Feed Rooms: Follow general instructions to remove animals from area to be treated. Thoroughly clean or dry clean surfaces, then wash the area manually or with pressure washer with a 1% BioBuster solution, saturating surfaces for a period of 10 minutes. Allow surfaces to air dry. Rinse waterers and feeders with potable water before reuse.]

[BOVINE PRODUCTION]:

[Follow General Instructions to remove livestock and pre-clean the area to be treated. Use a 1% solution of BioBuster to disinfect areas associated with bovine housing, hospital quarantine pens, feedlot facilities, and agricultural production equipment: such as trucks, rubber boots and associated livestock equipment and instruments. Saturate surfaces with a 1% solution of BioBuster with a cloth, mop, mechanical spray, or sponge and allow to sit for a period of 10 minutes. Allow surfaces to air dry. Rinse waterers and feeders with potable water before reuse.]

[COMPANION ANIMALS]:

[APPLICATIONS: Use a 1% solution of BioBuster as a "one step" cleaning and disinfecting procedure (Remove visible soil before application of the disinfecting/cleaning solution) for all surfaces, equipment, instruments, utensils and cages within Veterinary Medical Hospitals, quarantine areas, laboratory animal quarters, grooming and boarding facilities, kennels, catteries and animal transportation vehicles. Saturate surfaces with a 1% solution of BioBuster with a cloth, mop, spray, or sponge and allow to remain for a period of 10 minutes. Allow surfaces to air dry. Rinse waterers and feeders with potable water before reuse.

Do not immerse metal objects for long periods - 10 minutes is maximum contact time.]

All text in brackets [ ] is optional and may or may not be included on final label.

[GREENHOUSES AND HORTICULTURE]:

[BioBuster is intended to disinfect inanimate environmental surfaces: such as floors, walls, glass greenhouse structures, ventilation equipment, utensils, trays, containers, water systems, evaporative coolers, storage rooms, and vehicles in greenhouses and other horticultural settings prior to introduction or reintroduction of plants, seeds, or soil. Must not be applied to plants, seeds, or soil. If necessary, remove or cover these items prior to use of the product.]

[For surfaces and equipment including pots, flats, trays, pruning equipment, carts and transport vehicles]:
Sweep and remove all plant debris. Surfaces should be clean at the start and any visible soil should be removed from hard non-porous surfaces prior to treatment. Use a high pressure washer to wash all surfaces to remove loose dirt. Use a dilution of 1:100 (1.3 oz powder concentrate added to 1 gallon of water). Use a dilution of 1:50 or 2.6 oz. BioBuster per gallon of clean water if surfaces to be treated have not been pre-cleaned. Apply the solution with a mop, sponge, or power sprayer, to thoroughly wet all surfaces. Heavy growth of algae or fungi may have to be scrubbed off following application.

[For evaporative coolers: Surfaces sbould be visibly clean prior to treatment. Treat existing algae and slime contaminated surfaces with a 1:100 dilution of BioBuster.

[BioBuster may also be used to disinfect irrigation tanks and lines. Create a 1% stock solution. Run the 1% solution through the system or soak equipment in a 1% solution. Let stand for ten minutes and then flush the system with clean water.

[AQUACULTURE]:

[BioBuster is intended to disinfect inanimate environmental surfaces associated with aquaculture production including vehicles, dip nets, boots, waders, hoses, brushes and other similar equipment. BioBuster must not be applied directly to water.]

]

All text in brackets [ ] is optional and may or may not be included on a final label.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal. **STORAGE:** Store in a cool dry place in tightly closed container. Keep out of reach of children. Always replace lid after use. **PESTICIDE DISPOSAL:** Pesticide wastes may be hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance. **CONTAINER DISPOSAL: Nonrefillable container. Do not reuse or refill this container.** Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

Rivas, Lorena

From: Williams, Joseph
Sent: Thursday, October 31, 2019 4:55 PM
To: Hardy, Jacqueline
Cc: Rivas, Lorena; Hicks, Karen; ODell, Lindsay
Subject: RE: Late Acute Tox Bridging/Similarity Determination for EPA File 92589-R DP 453017

Hey Jacqie,

Looking at the available CSF (from 2006) for the cited product, compared to the proposed product, we find the products formulation substantially similar, thus allowing for the use of Acute Tox data/profile and labeling of the cited for the proposed.

From: Hardy, Jacqueline <Hardy.Jacqueline@epa.gov>
Sent: Friday, October 25, 2019 4:52 PM
To: Williams, Joseph <williams.joseph@epa.gov>
Cc: Rivas, Lorena <Rivas.Lorena@epa.gov>; Hicks, Karen <Hicks.Karen@epa.gov>
Subject: RE: Late Acute Tox Bridging/Similarity Determination for EPA File 92589-R DP 453017

LanXess bought Virkon S registration, so the new registration number is 39967-137. If you search under that registration number, you will find the CSF.

From: Williams, Joseph <williams.joseph@epa.gov>
Sent: Friday, October 25, 2019 4:25 PM
To: Hardy, Jacqueline <Hardy.Jacqueline@epa.gov>
Cc: Rivas, Lorena <Rivas.Lorena@epa.gov>; Hicks, Karen <Hicks.Karen@epa.gov>
Subject: RE: Late Acute Tox Bridging/Similarity Determination for EPA File 92589-R DP 453017

Do either of you have the CSF for Reg #778-91?

From: Hardy, Jacqueline <Hardy.Jacqueline@epa.gov>
Sent: Friday, October 25, 2019 4:14 PM
To: Williams, Joseph <williams.joseph@epa.gov>
Cc: Rivas, Lorena <Rivas.Lorena@epa.gov>; Hicks, Karen <Hicks.Karen@epa.gov>
Subject: FW: Late Acute Tox Bridging/Similarity Determination for EPA File 92589-R DP 453017

Hi Joseph

Below is the email string regarding the bean for 92589-R.
If you have any questions, let me know.

Jacquie

From: Hardy, Jacqueline
Sent: Thursday, October 17, 2019 10:46 AM
To: Karen Hicks <Hicks.Karen@epa.gov>
Cc: Rivas, Lorena <rivas.lorena@epa.gov>
Subject: FW: Late Acute Tox Bridging/Similarity Determination for EPA File 92589-R DP 453017

HI Karen

Below is the original email that I sent regarding this bean. It's a bridging determination that I don't believe will take a lot of time provided the formulations are truly similar.

If you have any questions, let me know.

Thanks,
Jacquie

From: Hardy, Jacqueline
Sent: Monday, September 23, 2019 11:30 AM
To: OPP AD CTT DP <OPP_AD_CTT_DP@epa.gov>
Cc: Rivas, Lorena <rivas.lorena@epa.gov>
Subject: Late Acute Tox Bridging/Similarity Determination for EPA File 92589-R DP 453017

HI Karen

Attached is a late bean for an acute tox similarity determination. The proposed product would like to use 778-91's acute tox data to support this product's hazard language and acute tox. data requirements.
If you have any questions or need additional information, let me know.

Jacquie

Rivas, Lorena

From: Pham, Thao
Sent: Wednesday, November 06, 2019 9:52 AM
To: Hardy, Jacqueline; Rivas, Lorena
Subject: RE: revised data matrix question for Biobuster

Hi Jacquie,

I talked with Kristen and as the registrant technically followed our pre-registration advice from 3 years ago, we can agree to a compromise to allow the companion pests without additional data in this instance.

However, feline calicivirus and the OIE organisms will still need to be removed from the label. Also, please convey that this is a case-by-case exception and this approach should not be used for future registrations. In addition, for future submissions, the applicant should include all relevant pre-submission correspondence with the agency with the original submission to help facilitate our review.

Thanks!

From: Hardy, Jacqueline <Hardy.Jacqueline@epa.gov>
Sent: Wednesday, November 06, 2019 8:35 AM
To: Pham, Thao <Pham.Thao@epa.gov>; Rivas, Lorena <Rivas.Lorena@epa.gov>
Subject: RE: revised data matrix question for Biobuster

Hi Tina

We just recently completed an amendment for the product which resulted in a number of viruses being added to the label. Attached is the data matrix unfortunately it isn't complete; it only lists the new data not all the data generated to support this products registration. Therefore, I've also included the summary of data that has been submitted in support of this product from OPPIN Query.

If you have any questions, let me know.

Jacquie

From: Pham, Thao <Pham.Thao@epa.gov>
Sent: Tuesday, November 05, 2019 4:31 PM
To: Rivas, Lorena <Rivas.Lorena@epa.gov>
Cc: Hardy, Jacqueline <Hardy.Jacqueline@epa.gov>
Subject: RE: revised data matrix question for Biobuster

Hi Lorena,

Could you please help me get a copy of the data matrix for Virkon S? I just want to double check on the data set that we have for Virkon.

Thank you!
Tina

From: Melba Morrow <Melba.Morrow@toxcel.com>
Sent: Tuesday, November 05, 2019 3:32 PM
To: Pham, Thao <Pham.Thao@epa.gov>; Hardy, Jacqueline <Hardy.Jacqueline@epa.gov>

Cc: Nelson Cornwell <Nelson.Cornwell@toxcel.com>; Rivas, Lorena <Rivas.Lorena@epa.gov>; Connie Welch-DuJardin <Connie.Welch-DuJardin@toxcel.com>
Subject: RE: revised data matrix question for Biobuster

Hi all,
In constructing the data matrix, we have found that Virkon-S has no data to cite for the viruses that we are listing. For the ones where we have data, there is no need to cite their studies and we will not be listing OIE pathogens for which Virkon has developed data.

What would we be citing in the absence of data from Virkon?

From: Pham, Thao [mailto:Pham.Thao@epa.gov]
Sent: Tuesday, November 5, 2019 1:07 PM
To: Melba Morrow <Melba.Morrow@toxcel.com>
Cc: Nelson Cornwell <Nelson.Cornwell@toxcel.com>; Rivas, Lorena <Rivas.Lorena@epa.gov>
Subject: RE: revised data matrix question for Biobuster

Hi Melba,

The studies that were conducted using Biobuster should still be included on the data matrix. For viruses that were not tested using Biobuster, you should cite from Virkon S.

Thanks!
Tina

From: Melba Morrow <Melba.Morrow@toxcel.com>
Sent: Tuesday, November 05, 2019 12:25 PM
To: Pham, Thao <Pham.Thao@epa.gov>
Cc: Nelson Cornwell <Nelson.Cornwell@toxcel.com>
Subject: revised data matrix question for Biobuster

Hi Tina,
Thanks for your response regarding the viruses that can be claimed on the Biobuster Label. I am currently revising the viral claims and including the other edits that were requested in your data review. We were wondering what needs to be done to the data matrix, since it lists studies that were actually conducted to support efficacy.

We would like to complete your request before COB today; however, in the event that we carry the action over until tomorrow morning, please send additional requests to Nelson Cornwell. He has been included on this email. I will be off site at a meeting tomorrow.

Thanks again for your help.
Melba

Rivas, Lorena

From: Hardy, Jacqueline
Sent: Wednesday, November 06, 2019 9:10 AM
To: Rivas, Lorena
Subject: FW: revised data matrix question for Biobuster

In regards to data comp, is Biobuster utilizing registered sources for the active ingredients? If not, did the company submit generic data matrices for the actives?

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Sent: Wednesday, November 06, 2019 8:35 AM
To: Pham, Thao; Rivas, Lorena
Subject: RE: revised data matrix question for Biobuster
Attachments: 8570-35 virkon S Internal 20181129 Signed.pdf; Virkon S_39967-137_OPPINQuery Studies.pdf

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Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date 11/29/2018	EPA Reg No./File Symbol 39967-137	Page 1 of 2
Applicant's/Registrant's Name & Address LANXESS CORPORATION, 111 RIDC PARK WEST DR., PITTSBURGH, PA 15275	Product Virkon(TM) S	

Ingredient Potassium peroxymonosulfate, sodium chloride

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
OCSPP 810.2200 (2018)	Virucidal Efficacy of a Disinfectant for Use on Inanimate	50735101	LANXESS CORPORATION	OWN	Volume 1
	Environment. Surfaces - Avian Adenovirus type 2				
OCSPP 810.2200 (2018)	Virucidal Efficacy of a Disinfectant for Use on Inanimate	50735102	LANXESS CORPORATION	OWN	Volume 2
	Environment. Surfaces -Avian Infectious Bronchitis virus				
OCSPP 810.2200 (2018)	Virucidal Efficacy of a Disinfectant for Use on Inanimate	50735103	LANXESS CORPORATION	OWN	Volume 3
	Environment. Surfaces - Avian Influenza A (H7N9) virus				
OCSPP 810.2200 (2018)	Virucidal Efficacy of a Disinfectant for Use on Inanimate	50735104	LANXESS CORPORATION	OWN	Volume 4
	Environ.Surfaces-Avian Influenza A (H7N9) virus (5C)				
OCSPP 810.2200 (2018)	Virucidal Efficacy of a Disinfectant for Use on Inanimate	50735105	LANXESS CORPORATION	OWN	Volume 5
	Environment. Surfaces - Avian Reovirus				
OCSPP 810.2200 (2018)	Virucidal Efficacy of a Disinfectant for Use on Inanimate	50735106	LANXESS CORPORATION	OWN	Volume 6
	Environment. Surfaces - Canine Parvovirus				
OCSPP 810.2200 (2018)	Virucidal Efficacy of a Disinfectant for Use on Inanimate	50735107	LANXESS CORPORATION	OWN	Volume 7
	Environment. Surfaces - Infectious Bursal Disease virus				

Signature	Name and Title	Date
Ellen P	Regulatory Affairs & Product Stewardship Consultant	11/29/2018

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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Ingredient Potassium peroxymonosulfate, sodium chloride

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
OCSPP 810.2200 (2018)	Virucidal Efficacy of a Disinfectant for Use on Inanimate	50735108	LANXESS CORPORATION	OWN	Volume 8
	Environment. Surfaces-Infectious Laryngotracheitis virus				
OCSPP 810.2200 (2018)	Virucidal Efficacy of a Disinfectant for Use on Inanimate	50735109	LANXESS CORPORATION	OWN	Volume 9
	Environment. Surfaces-Porcine Epidemic Diarrhea Virus				
OCSPP 810.2200 (2018)	Virucidal Efficacy of a Disinfectant for Use on Inanimate	50735110	LANXESS CORPORATION	OWN	Volume 10
	Environment. Surfaces - Porcine Respiratory &				
	Reproductive Syndrome (PRRS) virus				
DCSPP 810.2200 (2018)	Virucidal Efficacy of a Disinfectant for Use on Inanimate	50735111	LANXESS CORPORATION	OWN	Volume 11
	Environment. Surfaces - Porcine Rotavirus				

Signature	Name and Title	Date
Ellen P	Regulatory Affairs & Product Stewardship Consultant	11/29/2018

Study Information For
Product Registration - Section 3
39967-137

MRID	Citation	Receipt Date
41052200	A.H. Robbins Co. (1989) Submission of Toxicity and Product Chemis- try Data to Support the Continued Registration for Sergeant's Skip-Flea Plus. Transmittal of 10 studies.	04-Apr-1989
41052201	A.H. Robins Co. (1988) Product Chemistry Data for Sergeant's Skip- Flea Plus. Unpublished study. 9 p.	04-Apr-1989
41052202	Gabriel, D. (1988) Flea & Tick Shampoo, Lot G572-168...Acute Oral Toxicity, LD50--Rats: Biosearch Project No. 88-6196A. Unpub- lished study prepared by Biosearch, Inc. 8 p.	04-Apr-1989
41052203	Gabriel, D. (1988) Flea & Tick Shampoo, Lot 0572-168...Acute Dermal Toxicity, LD50--Rahbits: Biosearch Project No. 88-6196A. Unpub- lished study prepared by Biosearch, Inc. 8 p.	04-Apr-1989
41052204	Reilly, C. (1988) Flea & Tick Shampoo, Lot No. G-572-168... Primary Eye Irritation--Rabbits: Biosearch Project No. 88-6055A. Unpub- lished study prepared by Biosearch, Inc. 11 p.	04-Apr-1989
41052205	Gabriel, D. (1988) Flea & Tick Shampoo, Lot G572-168...Primary Skin Irritation--Rabbits: Biosearch Project No. 88-6196A. Unpub- lished study prepared by Biosearch, Inc. 9 p.	04-Apr-1989
41052206	Gallis, J. (1988) Flea & Tick Shampoo, Lot G572-168...Guinea Pig Dermal Sensitization--Modified Buehler Method: Biosearch Project No. 88-6196A. Unpublished study prepared by Biosearch, Inc. 10 p.	04-Apr-1989
41052207	Gallis, J. (1988) Guinea Pig Dermal Sensitization--Modified Buehler Method--Positive Control: Biosearch Project No. 88-6196A. Unpublished study prepared by Biosearch, Inc. 10 p.	04-Apr-1989
41052208	Boyd, J. (1988) Comparative Effectiveness of Various Shampoo Formu- lations Against Fleas and Ticks on Dogs and Clinical Observa- tions prior to and after Treatment: P.A.C.E. No. 10-286-0588. Unpublished study prepared by P.A.C.E. International. 233 p.	04-Apr-1989
41052209	Hershman, R. (1986) Primary Eye Irritation--Rabbits: Lambert Kay Pro-Coat Tearless Shampoo for Cats: Project No. 86-5223A. Unpublished study prepared by Biosearch, Inc. 10 p.	04-Apr-1989
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Total Rows: 118		

Rivas, Lorena

From: Pham, Thao
Sent: Tuesday, November 05, 2019 8:01 AM
To: Hardy, Jacqueline; Rivas, Lorena
Cc: Willis, Kristen
Subject: RE: Late Acute Tox Bridging/Similarity Determination for EPA File 92589-R DP 453017

Hi Jacquie / Lorena,

We're on board with this approach. We would need to see the revised data matrix and label.

- Labeling should be revised to match the Virkon S product – organisms tested without hard water should specify "dilute with deionized water".
- Avian influenza strain should be revised to H5N1 (not H7N1).

The additional information that Melba provided for pidgeon adenovirus supports the claim for this virus.

Thanks!
Tina

From: Hardy, Jacqueline <Hardy.Jacqueline@epa.gov>
Sent: Friday, November 01, 2019 6:45 AM
To: Pham, Thao <Pham.Thao@epa.gov>; Willis, Kristen <Willis.Kristen@epa.gov>
Cc: Rivas, Lorena <Rivas.Lorena@epa.gov>
Subject: FW: Late Acute Tox Bridging/Similarity Determination for EPA File 92589-R DP 453017

Hi Tina/Kristen

Below is Joseph's determination that Biobuster's formulation is substantially similar to Virkon S's formulation. I will reach out to the consultant and request a revised data matrix where they are citing Virkon's data. Is there any additional information that you need to complete your review?

Thanks,
Jacquie

From: Williams, Joseph <williams.joseph@epa.gov>
Sent: Thursday, October 31, 2019 4:55 PM
To: Hardy, Jacqueline <Hardy.Jacqueline@epa.gov>
Cc: Rivas, Lorena <Rivas.Lorena@epa.gov>; Hicks, Karen <Hicks.Karen@epa.gov>; ODell, Lindsay <odell.lindsay@epa.gov>
Subject: RE: Late Acute Tox Bridging/Similarity Determination for EPA File 92589-R DP 453017

Hey Jacqie,

Looking at the available CSF (from 2006) for the cited product, compared to the proposed product, we find the products formulation substantially similar, thus allowing for the use of Acute Tox data/profile and labeling of the cited for the proposed.

From: Hardy, Jacqueline <Hardy.Jacqueline@epa.gov>
Sent: Friday, October 25, 2019 4:52 PM

To: Williams, Joseph <williams.joseph@epa.gov>
Cc: Rivas, Lorena <Rivas.Lorena@epa.gov>; Hicks, Karen <Hicks.Karen@epa.gov>
Subject: RE: Late Acute Tox Bridging/Similarity Determination for EPA File 92589-R DP 453017

LanXess bought Virkon S registration, so the new registration number is 39967-137. If you search under that registration number, you will find the CSF.

From: Williams, Joseph <williams.joseph@epa.gov>
Sent: Friday, October 25, 2019 4:25 PM
To: Hardy, Jacqueline <Hardy.Jacqueline@epa.gov>
Cc: Rivas, Lorena <Rivas.Lorena@epa.gov>; Hicks, Karen <Hicks.Karen@epa.gov>
Subject: RE: Late Acute Tox Bridging/Similarity Determination for EPA File 92589-R DP 453017

Do either of you have the CSF for Reg #778-91?

From: Hardy, Jacqueline <Hardy.Jacqueline@epa.gov>
Sent: Friday, October 25, 2019 4:14 PM
To: Williams, Joseph <williams.joseph@epa.gov>
Cc: Rivas, Lorena <Rivas.Lorena@epa.gov>; Hicks, Karen <Hicks.Karen@epa.gov>
Subject: FW: Late Acute Tox Bridging/Similarity Determination for EPA File 92589-R DP 453017

Hi Joseph

Below is the email string regarding the bean for 92589-R.
If you have any questions, let me know.

Jacquie

From: Hardy, Jacqueline
Sent: Thursday, October 17, 2019 10:46 AM
To: Karen Hicks <Hicks.Karen@epa.gov>
Cc: Rivas, Lorena <rivas.lorena@epa.gov>
Subject: FW: Late Acute Tox Bridging/Similarity Determination for EPA File 92589-R DP 453017

HI Karen

Below is the original email that I sent regarding this bean. It's a bridging determination that I don't believe will take a lot of time provided the formulations are truly similar.

If you have any questions, let me know.

Thanks,
Jacquie

From: Hardy, Jacqueline
Sent: Monday, September 23, 2019 11:30 AM
To: OPP AD CTT DP <OPP_AD_CTT_DP@epa.gov>
Cc: Rivas, Lorena <rivas.lorena@epa.gov>
Subject: Late Acute Tox Bridging/Similarity Determination for EPA File 92589-R DP 453017

HI Karen

Attached is a late bean for an acute tox similarity determination. The proposed product would like to use 778-91's acute tox data to support this product's hazard language and acute tox. data requirements.
If you have any questions or need additional information, let me know.

Jacquie

Rivas, Lorena

From: Pham, Thao
Sent: Tuesday, November 05, 2019 1:07 PM
To: Melba Morrow
Cc: Nelson Cornwell; Rivas, Lorena
Subject: RE: revised data matrix question for Biobuster

Hi Melba,

The studies that were conducted using Biobuster should still be included on the data matrix. For viruses that were not tested using Biobuster, you should cite from Virkon S.

Thanks!
Tina

From: Melba Morrow <Melba.Morrow@toxcel.com>
Sent: Tuesday, November 05, 2019 12:25 PM
To: Pham, Thao <Pham.Thao@epa.gov>
Cc: Nelson Cornwell <Nelson.Cornwell@toxcel.com>
Subject: revised data matrix question for Biobuster

Hi Tina,
Thanks for your response regarding the viruses that can be claimed on the Biobuster Label. I am currently revising the viral claims and including the other edits that were requested in your data review. We were wondering what needs to be done to the data matrix, since it lists studies that were actually conducted to support efficacy.

We would like to complete your request before COB today; however, in the event that we carry the action over until tomorrow morning, please send additional requests to Nelson Cornwell. He has been included on this email. I will be off site at a meeting tomorrow.

Thanks again for your help.
Melba

From: Nelson Cornwell
To: Eronini, Lynette
Cc: Connie Welch-DuJardin; Melba Morrow; Alan Katz
Subject: RE: 92589-R_D453013_BioBuster
Date: Tuesday, October 29, 2019 8:56:33 AM
Attachments: 830.6320 Corrosion Characteristics for BioBuster.pdf

Good Morning Lynette,

I apologize for the delay.

Please find attached the Corrosion Characteristics for BioBuster.

Best regards,
Nelson

From: Nelson Cornwell
Sent: Monday, October 28, 2019 4:51 PM
To: Eronini, Lynette <Eronini.Lynette@epa.gov>
Cc: Connie Welch-DuJardin <Connie.Welch-DuJardin@toxcel.com>; Melba Morrow <Melba.Morrow@toxcel.com>; Alan Katz <Alan.Katz@toxcel.com>
Subject: RE: 92589-R_D453013_BioBuster

Hi Lynette,

I hope this finds you well.

I have attached the updated label (track changes and clean), CSFs, and Oxidation/Reduction.

We are still awaiting a response concerning Corrosion Characteristics. The lab that was used is located in India and with the time difference and the holiday (Festival of Lights is what I'm being told) there has been a delay. We are hopeful we can get a statement from them in the morning.

The CSFs are password protected. I will send the password in a separate email.

Please let us know what else you may need from us.

Best regards,
Nelson

From: Eronini, Lynette [mailto:Eronini.Lynette@epa.gov]
Sent: Tuesday, October 22, 2019 11:25 AM
To: Alan Katz <Alan.Katz@toxcel.com>
Cc: Melba Morrow <Melba.Morrow@toxcel.com>; Rivas, Lorena <Rivas.Lorena@epa.gov>; Hardy, Jacqueline <Hardy.Jacqueline@epa.gov>
Subject: RE: 92589-R_D453013_BioBuster

Alan and Melba,
Thanks for making it possible to have a conference call with no internet and telephonic connection at your agency. If there are questions concerning the issues that were discussed, please contact me. I look to receive updated/corrected documents between Friday, October 25, 2019 and Monday, October 28, 2019.

Lynette T. Umez-Eronini
Antimicrobials Division
Office of Pesticide Program
703-347-0132

From: Eronini, Lynette
Sent: Monday, October 21, 2019 3:46 PM
To: Alan Katz <Alan.Katz@toxcel.com>
Subject: RE: 92589-R_D453013_BioBuster

Great!
Lynette

From: Alan Katz <Alan.Katz@toxcel.com>
Sent: Monday, October 21, 2019 3:33 PM
To: Eronini, Lynette <Eronini.Lynette@epa.gov>
Cc: Melba Morrow <Melba.Morrow@toxcel.com>; Hardy, Jacqueline <Hardy.Jacqueline@epa.gov>; Rivas, Lorena <Rivas.Lorena@epa.gov>; Nelson Cornwell <Nelson.Cornwell@toxcel.com>
Subject: RE: 92589-R_D453013_BioBuster

Lynette,

Thanks for your email message. We will call you between 10:00-10:30 AM tomorrow to discuss the issues that you mentioned.

Kind regards,
Alan

Alan C. Katz
PRESIDENT

toXcel LLC
7140 Heritage Village Plaza
Gainesville, VA 20155
USA
Ph (USA): +1 (703) 754-0248 ext. 8111
Ph (UK link): +44 (0) 20 7993 6957
Fax: +1 (703) 310-6950

www.toxcel.com

From: Eronini, Lynette [mailto:Eronini.Lynette@epa.gov]
Sent: Monday, October 21, 2019 3:11 PM
To: Alan Katz <Alan.Katz@toxcel.com>
Cc: Melba Morrow <Melba.Morrow@toxcel.com>; Hardy, Jacqueline <Hardy.Jacqueline@epa.gov>; Rivas, Lorena <Rivas.Lorena@epa.gov>
Subject: 92589-R_D453013_BioBuster

Alan Katz,
Thanks for returning my call. Please set up conference call with Melba Morrow, you and me and call me between 10 and 10:45 AM. on Tuesday, October 22, 2019 to discuss issues that are mentioned in the attachment.

Lynette T. Umez-Eronini
Antimicrobials Division
Office of Pesticide Program
703-347-0132

Ref. BVBV/2019-20/
Date: 29.10.2019

To Whom it may concern

Certified that we at B.V. Bio-Corp Pvt. Ltd, are packing the product Bio-Buster in HDPE containers. On long time storage study, 3 months beyond expiry date, we found no corrosion occurred to HDPE container. We confirm that the product is compatible with HDPE material and doesn't corrode the containers.

For **B.V. Bio-Corp Pvt. Ltd.**

Dy. General Manager
Authorized Signatory

October 18, 2019

To: Dr. Connie B. Welch-Du Jardin

Concerns for 92589-R_D453013_BioBuster

The following need to be corrected or upgraded;

1. The CSFs are not acceptable for the reasons as follows;
   i) Uncleared fragrances colorants [redacted] nor is the amount listed in **box 13 a**.
   ii) The nominal concentrations of the active ingredients differ from those on the product label.
   iii) No support for non-EPA Standard certified limits for some of the inert ingredients.
   iv) 100% purity for NaCl is not supported by the 830.1700 Preliminary Analysis guideline (on pages 99 of 128 -105 of 1285 in MRID 50847901).
2. The **TOTAL** on the label does not add up to 100%.
3. The 830.6314 Oxidation/Reduction guideline need to address the product and not one component of the product.
4. The 830.6320 Corrosion Characteristics is not addressed in MRID 50847902 and does not mention the characteristic of product container after the storage period.

I will call to discuss the above issues.

Lynette T. Umez-Eronini

Decision #: 551035
DP #: (453013)
PRIA
Parent DP #:
Submission #: 1034761
E-Sub #: 39226

DATA PACKAGE BEAN SHEET

Date: 02-Jul-2019

* * * Registration Information * * *

Registration: 92589-R - BioBuster

Company: 92589 - ENVYSS, LLC

Risk Manager: RM 34 - Jacqueline Hardy - 703-308-6416 Room# PY1 S-8317

Risk Manager Reviewer: Lorena Rivas LRIVAS

Sent Date: PRIA Due Date: 06-Nov-2019 Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (A540) New end use product;FIFRA §2(mm) uses only;up to 25 public health organisms;

Ingredients: 013905, Sodium chloride(1.5%)

063604, Potassium peroxymonosulfate(21.41%)

* * * Data Package Information * * *

Expedite: ● Yes ○ No Date Sent: 28-Jun-2019 Due Back:

DP Ingredient: 013905, Sodium chloride

063604, Potassium peroxymonosulfate

DP Title: Product Chemistry

CSF Included: ● Yes ○ No Label Included: ● Yes ○ No Parent DP #:

Assigned To	Date In	Date Out	
Organization: AD / PSB			Last Possible Science Due Date: 07-Oct-2019
Team Name: CTT			Science Due Date:
Reviewer Name:			Sub Data Package Due Date:
Contractor Name:			

* * * Studies Sent for Review * * *

Printed on Page 2

* * * Additional Data Package for this Decision * * *

Can be printed on its own page

* * * Data Package Instructions * * *

PRIA: New hospital Disinfectant
Electronic Submission - Pls go to Documentum for Info

Science Technical Screen Due Date: August 1, 2019
Please review the basic CSF and product chem data in MRID 50847901-50847902 for completeness

Data Evaluation
Please review the data and CSF to determine if its acceptable to support this product's registration

50847901	Toxcel, LLC (2019) BioBuster: Group A Product Chemistry. Unpublished study prepared by ToXcel, LLC. 154p.	830.1550/Product identity and composition	Not Reviewed (14-May-2019)
50847901	Toxcel, LLC (2019) BioBuster: Group A Product Chemistry. Unpublished study prepared by ToXcel, LLC. 154p.	830.1600/Description of materials used to produce the product	Not Reviewed (14-May-2019)
50847901	Toxcel, LLC (2019) BioBuster: Group A Product Chemistry. Unpublished study prepared by ToXcel, LLC. 154p.	830.1620/Description of production process	Not Reviewed (14-May-2019)
50847901	Toxcel, LLC (2019) BioBuster: Group A Product Chemistry. Unpublished study prepared by ToXcel, LLC. 154p.	830.1650/Description of formulation process	Not Reviewed (14-May-2019)
50847901	Toxcel, LLC (2019) BioBuster: Group A Product Chemistry. Unpublished study prepared by ToXcel, LLC. 154p.	830.1670/Discussion of formation of impurities	Not Reviewed (14-May-2019)
50847901	Toxcel, LLC (2019) BioBuster: Group A Product Chemistry. Unpublished study prepared by ToXcel, LLC. 154p.	830.1700/Preliminary analysis	Not Reviewed (14-May-2019)
50847901	Toxcel, LLC (2019) BioBuster: Group A Product Chemistry. Unpublished study prepared by ToXcel, LLC. 154p.	830.1750/Certified limits	Not Reviewed (14-May-2019)
50847901	Toxcel, LLC (2019) BioBuster: Group A Product Chemistry. Unpublished study prepared by ToXcel, LLC. 154p.	830.1600/Enforcement analytical method	Not Reviewed (14-May-2019)
50847902	Toxcel, LLC (2019) BioBuster: Group B Product Chemistry. Unpublished study prepared by Envyss, LLC. 24p.	830.6302/Color	Not Reviewed (14-May-2019)
50847902	Toxcel, LLC (2019) BioBuster: Group B Product Chemistry. Unpublished study prepared by Envyss, LLC. 24p.	830.6303/Physical state	Not Reviewed (14-May-2019)
50847902	Toxcel, LLC (2019) BioBuster: Group B Product Chemistry. Unpublished study prepared by Envyss, LLC. 24p.	830.6304/Odor	Not Reviewed (14-May-2019)
50847902	Toxcel, LLC (2019) BioBuster: Group B Product Chemistry. Unpublished study prepared by Envyss, LLC. 24p.	830.6313/Stability to normal and elevated temperatures, metels, and metal ions	Not Reviewed (14-May-2019)
50847902	Toxcel, LLC (2019) BioBuster: Group B Product Chemistry. Unpublished study prepared by Envyss, LLC. 24p.	830.6314/Oxidizing or reducing action	Not Reviewed (14-May-2019)
50847902	Toxcel, LLC (2019) BioBuster: Group B Product Chemistry. Unpublished study prepared by Envyss, LLC. 24p.	830.6315/Flammability	Not Reviewed (14-May-2019)
50847902	Toxcel, LLC (2019) BioBuster: Group B Product Chemistry. Unpublished study prepared by Envyss, LLC. 24p.	830.6316/Explodability	Not Reviewed (14-May-2019)
50847902	Toxcel, LLC (2019) BioBuster: Group B Product Chemistry. Unpublished study prepared by Envyss, LLC. 24p.	830.6317/Storage stability	Not Reviewed (14-May-2019)
50847902	Toxcel, LLC (2019) BioBuster: Group B Product Chemistry. Unpublished study prepared by Envyss, LLC. 24p.	830.6319/Miscibility	Not Reviewed (14-May-2019)
50847902	Toxcel, LLC (2019) BioBuster: Group B Product Chemistry. Unpublished study prepared by Envyss, LLC. 24p.	830.6320/Corrosion characteristics	Not Reviewed (14-May-2019)
50847902	Toxcel, LLC (2019) BioBuster: Group B Product Chemistry. Unpublished study prepared by Envyss, LLC. 24p.	830.6321/Dielectric breakdown voltage	Not Reviewed (14-May-2019)
50847902	Toxcel, LLC (2019) BioBuster: Group B Product Chemistry. Unpublished study prepared by Envyss, LLC. 24p.	830.7000/pH	Not Reviewed (14-May-2019)
50847902	Toxcel, LLC (2019) BioBuster: Group B Product Chemistry. Unpublished study prepared by Envyss, LLC. 24p.	830.7100/Viscosity	Not Reviewed (14-May-2019)
50847902	Toxcel, LLC (2019) BioBuster: Group B Product Chemistry. Unpublished study prepared by Envyss, LLC. 24p.	830.7200/Melting point/melting range	Not Reviewed (14-May-2019)

DP#: (453013) *** Studies Sent for Review *** Decision#: (551035)

50847902		Toxcel, LLC (2019) BioBuster: Group B Product Chemistry. Unpublished study prepared by Envyss, LLC. 24p.	830.7220/Boiling point/boiling range	Not Reviewed (14-May-2019)
50847902		Toxcel, LLC (2019) BioBuster: Group B Product Chemistry. Unpublished study prepared by Envyss, LLC. 24p.	830.7300/Density/relative density	Not Reviewed (14-May-2019)
50847902		Toxcel, LLC (2019) BioBuster: Group B Product Chemistry. Unpublished study prepared by Envyss, LLC. 24p.	830.7370/Dissociation constants in water	Not Reviewed (14-May-2019)
50847902		Toxcel, LLC (2019) BioBuster: Group B Product Chemistry. Unpublished study prepared by Envyss, LLC. 24p.	830.7550/Partition coefficient (n-octanol/water), shake flask method	Not Reviewed (14-May-2019)
50847902		Toxcel, LLC (2019) BioBuster: Group B Product Chemistry. Unpublished study prepared by Envyss, LLC. 24p.	830.7840/Water solubility: Column elution method, shake flask method	Not Reviewed (14-May-2019)
50847902		Toxcel, LLC (2019) BioBuster: Group B Product Chemistry. Unpublished study prepared by Envyss, LLC. 24p.	830.7950/Vapor pressure	Not Reviewed (14-May-2019)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

EPA United States Environmental Protection Agency **Office of Pesticide Programs**

MEMORANDUM

11/1/2019

SUBJECT: Product Chemistry Review for **BioBuster** EPA Reg. No.: **92589-R**

FROM: Lynette T. Umez-Eronini
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

THRU: Karen P. Hicks, Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

TO: Jacqueline Hardy, PM Team 34 / Lorena Rivas
Regulatory Management Branch II
Antimicrobials Division (7510P)

Registrant: Envyss LLC
Action code: A540
Agency Due Date: 11/6/2019
DP No.: 453013
Submission No.: 1034761
E-Sub No.: 39226
Classification: EP
Process: Integrated system
Pesticide type: Antimicrobial

MRID(s):50847901, 50847902

Formulation from label			
PC code(s)	CAS #(s)	Active Ingredient(s)	% weight
063604	10058-23-8	Potassium peroxymonosulfate	21.40
013905	7647-14-5	Sodium chloride	1.50
		Other Ingredients	77.10
		Total	100.00

I. BACKGROUND

The Registrant, Envyss LLC, has submitted an application for pesticide registration for their product: BioBuster EPA Reg. No. 92589-R.

II. RELEVANT DOCUMENTS

	RECEIVED	N/A
EPA FORM 8570-1 Application for Pesticide Registration (5/13/2019)	☒	☐
EPA FORM 8570-27 – Formulator's Exemption Statement	☐	☒
EPA FORM 8570-34 – Certification with Respect to Citation of Data (5/13/2019)	☒	☐
EPA FORM 8570-35 – Data Matrix (5/13/2019)	☒	☐
Cover letter (5/19/2019)	☒	☐
Transmittal document (5/13/2019)	☒	☐
Proposed CSF BASIC and ALTERNATE 1, (11/1/2019)	☒	☐
Proposed label, 10/28/2019	☒	☐
Registrant's letter, Ref. BVBV/2019-20/ dated (10/29/2019)	☒	☐
	☐	☐
REFERENCED: CSF	--	
Comments:		

III. FINDINGS

a. Product Formulation:

	TGAI	MUP	EUP	Food use	Non-food use
Non-integrated	☐	☐	☐	☐	☐
Integrated	☐	☐	☒	☐	☒

Active Ingredients(s)	Nominal	Upper limit	Lower limit
Potassium peroxymonosulfate	21.4	22.0	20.8
Sodium chloride	1.5	1.56	1.41
	YES	**NO**	**N/A**
1. The certified limits of all ingredients are within 40 CFR standard certified limits.	☒	☐	☐
2. Wider certified limits were requested and rationale was accepted.	☐	☐	☒
3. The nominal concentration(s) of the active ingredient is in agreement with the label.	☒	☐	☐

4. The chemical IDs and analytical information for density, pH, and flammability are consistent with Series 830 Group B data.	☒	☐	
5. All inert ingredients are approved for non-food use pesticide formulations.	☒	☐	☐
6. The impurities present >0.1% are identified.	☐	☐	☒
7. Impurities of toxicological significance have an upper certified limit.	☐	☐	☒

b. Product Label:

	Yes	NO	N/A
The formula contains one of the following:			
1. 10% or more of petroleum distillate	☐	☒	☐
2. 1.0% or more of methyl alcohol	☐	☒	☐
3. Sodium nitrite at any level	☐	☒	☐
4. A toxic list 1 inert at any level	☐	☒	☐
5. Arsenic in any form	☐	☒	☐
6. If yes to 1-5, then the inert ingredient list contains a relevant footnote	☐	☐	☒
7. Appropriate warning statements regarding flammability or explosive characteristics of the product are included on the label	☐	☐	☒
8. The storage and disposal instructions for the pesticide container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses.	☒	☐	☐
9. The product requires an expiration date at which time the nominal concentration falls below the lower certified limit.	☐	☐	☒

IV. Additional Findings

1. Basic and Alternate 1 CSFs dated 11/1/2019 are acceptable.
2. Group A product chemistry data requirements applicable to end-use product have been met (see MRID 50847901 on Table A below).
3. Group B product chemistry data requirements applicable to end-use product have been met (see MRID 50847902 on Table B below).
   Note: The 830.6317 Storage Stability and 830.6320 Corrosion Characteristics studies were conducted at 3, 6, 9, 12, 15, 18, and 24 months and 30°C ± 2°C (MRID 50847902). The concentrations of active ingredients were found to lie within EPA Standard certified limits over the duration of the studies. Registrant's letter dated 10/29/2019 confirmed that the product is compatible with its HDPE container and does not corrode the container for the duration of and 3 months beyond the expiry date (same as 24 months study period).

V. Conclusion

The Product Science Branch of Antimicrobials Division finds Group A and B Product Chemistry Data requirements have been met. Basic and Alternate 1 CSFs dated 11/1/2019 are acceptable.

VI. Table A:
Series 830 guidelines – Group A

OPPTS#	Name	Status	MRID
830.1550	Product Identity & Composition	Acceptable	50847901
830.1600	Description of materials	Acceptable	50847901
830.1620	Description of production process	Acceptable	50847901
830.1650	Description of formulation process	Acceptable	50847901
830.1670	Discussion of formation of impurities	Acceptable	50847901
830.1700	Preliminary analysis	Acceptable	50847901
830.1750	Certified limits	Requires upgrading	CSF, dated 10/31/2019
830.1800	Enforcement analytical method	Acceptable	50847901
830.1900	Submittal of samples	Acceptable	50847901 50472810

VII. Table B: Series 830 guidelines – Group B

OPPTS#	Name	Study Findings/Comment	Status	MRID
830.6302	Color	Not required for end use product	Not applicable	N/A
830.6303	Physical state	solid	Acceptable	50847902
830.6304	Odor	Not required for end use product. Registrant reported a lemon perfume scent.	Not applicable	N/A 50847902
830.6313	Stability to normal & elevated temperatures, metals & metal ions	The product is not TGAI	Not applicable	N/A
830.6314	Oxidation/Reduction	BioBuster is an oxidizer.	Acceptable	50847902
830.6315	Flammability	N/A. The product does not contain combustible liquids.	Acceptable	50847902
830.6316	Explodability	N/A. The product is not potentially explosive and does not possess any explosive properties.	Acceptable	50847902
830.6317	Storage stability	The concentrations of active ingredients were found to lie within EPA Standard certified limits over the duration of the studies.	Acceptable	50847902
830.6319	Miscibility	N/A. The product is not an emulsifiable liquid and will not be diluted with petroleum solvents.	Acceptable	50847902
830.6320	Corrosion characteristics	The product is compatible with HDPE container and does not corrode the container for the duration and 3 months beyond the expiry date (same as 24 months study period).	Acceptable	50847902 & Registrant's letter, dated 10/29/2019
830.6321	Dielectric breakdown voltage	N/A. Product is not a liquid to be used around electrical equipment.	Acceptable	50847902
830.7000	pH	2.10 -2.50	Acceptable	50847902
830.7050	UV/Visible absorption	Not required for MUP or EP	Not applicable	N/A
830.7100	Viscosity	N/A. The product is not a liquid.	Acceptable	50847902

830.7200	Melting point	Not required for MUP or EP	Not applicable	N/A
830.7220	Boiling point	Not required for MUP or EP	Not applicable	N/A
830.7300	Density/relative	1.15 – 1.30 g/cm^3	Acceptable	50847302
830.7370	Dissociation constants in water	Not required for MUP or EP	Not applicable	N/A
830.7520	Particle size	Not required for MUP or EP	Not applicable	N/A
830.7550/ 7560/ 7570	Partition coefficient	Not required for MUP or EP	Not applicable	N/A
830.7840/ 7860	Water solubility	Not required for MUP or EP	Not applicable	N/A
830.7950	Vapor pressure	Not required for MUP or EP	Not applicable	N/A

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

Date: October 2, 2019

Subject: Efficacy Review for Biobuster, EPA File Symbol: 92589-R
(DP Barcode: 453014, E-Submission: 39226)

From: Thao Pham
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510P)

Thru: Kristen Willis, Chief
Product Science Branch
Antimicrobials Division (7510P)
Date Signed: October 16, 2019

To: Jacqueline Hardy, Team 34 / Lorena Rivas
Regulatory Management Branch II
Antimicrobials Division (7510P)

Applicant: Envyss, LLC.
c/o: Toxcel – Toxicology & Regulatory Affairs
7140 Heritage Village Plaza
Gainesville, VA 20155-3061

Formulation from the Label:

Active Ingredient(s)	% by wt.
Potassium peroxymonosulfate	21.41%
Sodium chloride	1.50%
Other Ingredients	77.10%
Total	100.0%

I BACKGROUND

Product Description (as packaged, as applied): Liquid concentrate

Submission type: New registration

Currently registered efficacy claim(s): n/a

Requested action(s): Register as a broad-spectrum disinfectant (bactericide, virucide)

Documents considered in this review:

- Letter from applicant to EPA dated May 13, 2019
- Data Matrix (EPA Form 8570-35)
- 22 efficacy studies (MRID 50847903-50847924)
- Proposed label dated 08/09/19
- Confidential Statement of Formula (EPA Form 8670-4) dated 5/10/2019
- Volume 1 - Additional Information to Support the Certificate of Analysis in BioBuster's (EPA File Symbol 92589-R) Efficacy Studies, submitted in response to the technical screen.

II PROPOSED DIRECTIONS FOR USE

"GENERAL INSTRUCTIONS — FARM PREMISES, ANIMAL HOUSING BUILDINGS AND FARM EQUIPMENT

1. Remove all animals and feed from premises, vehicles and enclosures. Remove all litter and manure from floors, walls and surfaces of barns, pens, stalls, chutes and other facilities and fixtures occupied or traversed by animals. Empty all troughs, racks, and other feeding and watering appliances.
2. Thoroughly clean all surfaces with detergent and rinse with water.
3. Saturate all surfaces with the appropriate disinfection solution. Surfaces must remain wet for 10 minutes.
4. Immerse all animal handling equipment and forks, shovels, and scrapers used for removing litter and manure in the appropriate disinfection solution for 10 minutes. Allow to air dry.
5. Ventilate buildings and other closed spaces. Do not house animals or livestock or use equipment until the disinfection solution has been absorbed, set, or dried.
6. Thoroughly scrub treated feed racks, troughs, automatic feeders, and waterers with detergent and rinse with potable water before reuse.

BIOBUSTER MIXING INSTRUCTIONS:
To mix the appropriate use-diluted solution of BioBuster, first identify the percent solution desired. Second, fill a clean container with the volume of water for the desired percent solution and then add the associated quantity of powder (using the provided scoop) found in the following table. One scoop (1.3 ounces of powder) added to one gallon of water will yield a 1% solution.

Quantity of Water	0.5% Solution	1% Solution	2% Solution
1 Quart	0.15 ounces	0.3 ounces	0.7 ounces
1 Gallon	0.65 ounces	1.3 ounces	2.7 ounces
10 Gallons	6.7 ounces	13.4 ounces	26.7 ounces
50 Gallons	33.4 ounces	66.8 ounces	133.5 ounces

Solutions are stable for 7 days. 10 minutes is maximum necessary contact time. One gallon of solution is sufficient to treat 135 sq. ft.

III STUDY SUMMARIES

1.	MRID	50847903	Study Completion Date:	05/01/18
Study Objective		Disinfectant		
Testing Lab; Lab Study ID		Microbac Laboratories, Inc.; 962-109		
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		*Aeromonas hydrophila* (ATCC 19570)		
Test Method		AOAC Use Dilution Method		
Application Method		Liquid		
Test Substance Preparation	Name/ID	Bio-Buster		
	Lots ☐ 1 ☒ 2 ☐ 3	BB-T016, BB-T017		
	Preparation	Tested concentration: LCL Dilution: 1.3 oz per gallon (36.85 g of test substance to 3785 mL of diluent) Diluent: 400 ppm AOAC hard water		
Soil load		5% fetal bovine serum		
Carrier type, # per lot		Stainless steel penicylinders, 10		
Test conditions		Contact time: 10 mins; Temp: 20-21°C; RH: 26-44%		
Neutralizer		Letheen broth		
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		Note: ATCC number on the cover page of the report is incorrect.		

2.	MRID	50847904	Study Completion Date:	04/18/18
Study Objective		Disinfectant – virucidal		
Testing Lab, Lab Study ID		Microbac Laboratories, Inc.; 962-101		
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		Bovine Viral Diarrhea Virus, Strain: NADL, American BioResearch Laboratories		
Indicator Cell Culture		MDBK cells (ATCC CCL-22)		
Test Method		Virucidal Hard Surface Efficacy Test		
Application Method		Liquid, 2.0 mL		
Test Substance Preparation	Name/ID	Bio-Buster		
	Lots ☐ 1 ☒ 2 ☐ 3	BB-T016, BB-T017		
	Preparation	Tested concentration: LCL Dilution: 1.3 oz per gallon (36.85 g of test substance per 3785 mL of water) Diluent: 400 ppm AOAC hard water		
Soil load		5% FBS		
Carrier type, # per lot		1 glass petri dish carrier per batch		
Test conditions		Contact time: 10 mins; Temp: 20.0°C; RH: 34.0-34.5%		
Neutralizer		MEM + 10% HS + 0.5% $Na_2S_2O_3$ + 0.5% Polysorbate 80 + 3% HEPES + 1% $NaHCO_3$ + 0.01N NaOH		
Reviewer comments		N/A		

(i.e. protocol deviations and amendments, retesting, control failures, etc.)	

3.	**MRID**	50847905	**Study Completion Date:**		04/30/18		
Study Objective		Disinfectant – virucidal					
Testing Lab, Lab Study ID		Microbac Laboratories, Inc.; 962-102					
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		Canine Parvovirus, Strain: Cornell-780916-80, ATCC VR-2017					
Indicator Cell Culture		CrFK cells (ATCC CCL-94)					
Test Method		Virucidal Hard Surface Efficacy Test					
Application Method		Liquid, 2.0 mL					
Test Substance Preparation	**Name/ID**	Bio-Buster					
	Lots ☐ 1 ☒ 2 ☐ 3	BB-T016, BB-T017					
	Preparation	Tested concentration: LCL Dilution: 1.3 oz per gallon (0.93 g of test substance per 99.07 mL of diluent) Diluent: 400 ppm AOAC hard water					
Soil load		5% FBS					
Carrier type, # per lot		1 glass petri dish carrier per batch					
Test conditions		**Contact time**	10 mins	**Temp**	20-21°C	**RH**	38.4-39.9%
Neutralizer		MEM + 10% FBS + 0.5% $Na_2S_2O_3$ + 0.5% Polysorbate 80 + 3% HEPES + 1% $NaHCO_3$ + 0.01N NaOH					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		N/A					

4.	**MRID**	50847906	**Study Completion Date:**		05/01/18		
Study Objective		Disinfectant					
Testing Lab; Lab Study ID		Microbac Laboratories, Inc.; 962-106					
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		*Listeria monocytogenes* (ATCC 984)					
Test Method		AOAC Use Dilution Method					
Application Method		Liquid					
Test Substance Preparation	**Name/ID**	Bio-Buster					
	Lots ☐ 1 ☒ 2 ☐ 3	BB-T016, BB-T017					
	Preparation	Tested concentration: LCL Dilution: 1.3 oz per gallon (36.85 g of test substance to 3785 mL of diluent) Diluent: 400 ppm AOAC hard water					
Soil load		5% fetal bovine serum					
Carrier type, # per lot		Stainless steel penicylinders, 10					
Test conditions		**Contact time**	10 mins	**Temp**	20-21°C	**RH**	26-44%
Neutralizer		Letheen broth					

Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)	N/A

5.	**MRID**	50847907	**Study Completion Date:**	05/01/18			
Study Objective		Disinfectant					
Testing Lab; Lab Study ID		Microbac Laboratories, Inc.; 962-111					
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		*Streptococcus pneumoniae* (ATCC 33400)					
Test Method		AOAC Use Dilution Method					
Application Method		Liquid					
Test Substance Preparation	**Name/ID**	Bio-Buster					
	Lots ☐ 1 ☒ 2 ☐ 3	BB-T016, BB-T017					
	Preparation	Tested concentration: LCL Dilution: 1.3 oz per gallon (36.85 g of test substance to 3785 mL of diluent) Diluent: 400 ppm AOAC hard water					
Soil load		5% fetal bovine serum					
Carrier type, # per lot		Stainless steel penicylinders, 10					
Test conditions		**Contact time**	10 mins	**Temp**	20-21°C	**RH**	26-44%
Neutralizer		Letheen broth + 5% defibrinated sheep's blood					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		N/A					

6.	**MRID**	50847908	**Study Completion Date:**	06/15/18			
Study Objective		Disinfectant – virucidal					
Testing Lab, Lab Study ID		Accuratus Lab Services; A25565					
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		Avian Influenza A (H5N1) virus, Strain: VNH5N1-PR8/CDC-RG, CDC #2006719965					
Indicator Cell Culture		MDCK cells (ATCC CCL-34)					
Test Method		Virucidal Hard Surface Efficacy Test					
Application Method		Liquid, 2.0 mL					
Test Substance Preparation	**Name/ID**	Bio-Buster					
	Lots ☐ 1 ☒ 2 ☐ 3	BB-T016, BB-T017					
	Preparation	Tested concentration: LCL Dilution: 1.3 oz per gallon (1 g of test substance per 102.70 mL of diluent) Diluent: 400 ppm AOAC hard water					
Soil load		5% FBS					
Carrier type, # per lot		1 glass petri dish carrier per batch					
Test conditions		**Contact time**	10 min	**Temp**	21.0°C	**RH**	51.94%

Neutralizer	Sephadex Gel Filtration Column
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)	Relative humidity was only reported for inoculation of the carriers, not during the exposure treatment time. RH should be reported for the treatment time.

7	**MRID**	50847909	**Study Completion Date:**	05/09/18		
Study Objective		Disinfectant				
Testing Lab; Lab Study ID		Microbac Laboratories, Inc.; 962-103				
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		*Campylobacter jejuni* (ATCC 33560)				
Test Method		AOAC Use Dilution Method				
Application Method		Liquid				
Test Substance Preparation	**Name/ID**	Bio-Buster				
	Lots ☐ 1 ☒ 2 ☐ 3	BB-T016, BB-T017				
	Preparation	Tested concentration: LCL Dilution: 1.3 oz per gallon (36.85 g of test substance to 3785 mL of diluent) Diluent: 400 ppm AOAC hard water				
Soil load		5% fetal bovine serum				
Carrier type, # per lot		Stainless steel penicylinders, 10				
Test conditions		**Contact time**	10 mins	**Temp**	20-21°C	**RH** 26-44%
Neutralizer		Letheen broth + 5% defibrinated sheep's blood				
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		N/A				

8.	**MRID**	50847910	**Study Completion Date:**	06/18/18		
Study Objective		Disinfectant				
Testing Lab; Lab Study ID		Accuratus Lab Services; A25531				
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		*Bordetella avium* (ATCC 35086)				
Test Method		AOAC Use Dilution Method				
Application Method		Liquid				
Test Substance Preparation	**Name/ID**	Bio-Buster				
	Lots ☐ 1 ☒ 2 ☐ 3	BB-T016, BB-T017				
	Preparation	Tested concentration: LCL Dilution: 1.3 oz per gallon (4.61 g of test substance to 473 mL of diluent) Diluent: 400 ppm AOAC hard water				
Soil load		5% fetal bovine serum				
Carrier type, # per lot		Stainless steel penicylinders, 10				
Test conditions		**Contact time**	10 mins	**Temp**	20.0°C	**RH** 49.1-52.3%

Neutralizer	Letheen broth + 0.1% sodium thiosulfate
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)	Relative humidity was only reported for inoculation of the carriers, not during the exposure treatment time. RH should be reported for the treatment time.

9.	**MRID**	50847911	**Study Completion Date:**	06/18/18		
Study Objective		Disinfectant				
Testing Lab; Lab Study ID		Accuratus Lab Services; A25532				
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		*Bordetella bronchiseptica* (ATCC 10580)				
Test Method		AOAC Use Dilution Method				
Application Method		Liquid				
Test Substance Preparation	**Name/ID**	Bio-Buster				
	Lots ☐ 1 ☒ 2 ☐ 3	BB-T016, BB-T017				
	Preparation	Tested concentration: LCL Dilution: 1.3 oz per gallon (4.61 g of test substance to 473 mL of diluent) Diluent: 400 ppm AOAC hard water				
Soil load		5% fetal bovine serum				
Carrier type, # per lot		Stainless steel penicylinders, 10				
Test conditions		**Contact time**	10 mins	**Temp**	20.5°C	**RH**	39.4-39.7%
Neutralizer		Letheen broth + 0.1% sodium thiosulfate				
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		Relative humidity was only reported for inoculation of the carriers, not during the exposure treatment time. RH should be reported for the treatment time.				

10.	**MRID**	50847912	**Study Completion Date:**	06/18/18		
Study Objective		Disinfectant				
Testing Lab; Lab Study ID		Accuratus Lab Services; A25533				
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		*Escherichia coli* O157:H7 (ATCC 35150)				
Test Method		AOAC Use Dilution Method				
Application Method		Liquid				
Test Substance Preparation	**Name/ID**	Bio-Buster				
	Lots ☐ 1 ☒ 2 ☐ 3	BB-T016, BB-T017				
	Preparation	Tested concentration: LCL Dilution: 1.3 oz per gallon (3.69 g of test substance to 378.5 mL of diluent) Diluent: 400 ppm AOAC hard water				
Soil load		5% fetal bovine serum				
Carrier type, # per lot		Stainless steel penicylinders, 10				
Test conditions		**Contact time**	10 mins	**Temp**	21.0°C	**RH**	36.4-36.5%

Neutralizer	Letheen broth + 0.1% sodium thiosulfate
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)	Relative humidity was only reported for inoculation of the carriers, not during the exposure treatment time. RH should be reported for the treatment time.

11.	**MRID**	50847913	**Study Completion Date:**	06/14/18			
Study Objective		Disinfectant – virucidal					
Testing Lab, Lab Study ID		Accuratus Lab Services; A25566					
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		Feline Infectious Peritonitis virus, Strain: FIPV-1146, P100; ATCC VR-2202					
Indicator Cell Culture		A-72 cells (ATCC CRL-1542)					
Test Method		Virucidal Hard Surface Efficacy Test					
Application Method		Liquid, 2.0 mL					
Test Substance Preparation	**Name/ID**	Bio-Buster					
	Lots ☐ 1 ☒ 2 ☐ 3	BB-T016, BB-T017					
	Preparation	Tested concentration: LCL Dilution: 1.3 oz per gallon (1 g of test substance per 102.70 mL of diluent) Diluent: 400 ppm AOAC hard water					
Soil load		5% FBS					
Carrier type, # per lot		1 glass petri dish carrier per batch					
Test conditions		**Contact time**	10 min	**Temp**	20.0°C	**RH**	50%
Neutralizer		Sephadex Gel Filtration column					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		Relative humidity was only reported for inoculation of the carriers, not during the exposure treatment time. RH should be reported for the treatment time.					

12.	**MRID**	50847914	**Study Completion Date:**	06/18/18
Study Objective		Disinfectant		
Testing Lab; Lab Study ID		Accuratus Lab Services; A25530		
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		*Xanthomonas campestris* (ATCC 11058)		
Test Method		AOAC Use Dilution Method		
Application Method		Liquid		
Test Substance Preparation	**Name/ID**	Bio-Buster		
	Lots ☐ 1 ☒ 2 ☐ 3	BB-T016, BB-T017		
	Preparation	Tested concentration: LCL Dilution: 1.3 oz per gallon (4.61 g of test substance to 473 mL of diluent) Diluent: 400 ppm AOAC hard water		
Soil load		5% fetal bovine serum		
Carrier type, # per lot		Stainless steel penicylinders, 10		

Test conditions	**Contact time**	10 mins	**Temp**	20.5°C	**RH**	46.8-52.4%
Neutralizer	Letheen broth + 0.1% sodium thiosulfate					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)	Relative humidity was only reported for inoculation of the carriers, not during the exposure treatment time. RH should be reported for the treatment time.					

13.	**MRID**	50847915	**Study Completion Date:**	05/17/18
Study Objective		Disinfectant		
Testing Lab; Lab Study ID		Accuratus Lab Services; A25297		
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		*Pseudomonas aeruginosa* (ATCC 15442)		
Test Method		AOAC Use Dilution Method		
Application Method		Liquid		
Test Substance Preparation	**Name/ID**	Bio-Buster		
	Lots ☐ 1 ☐ 2 ☒ 3	BB-T016, BB-T017, BB-T018		
	Preparation	Tested concentration: LCL Dilution: 1.3 oz per gallon (0.93 g of test substance to 99.07 mL of diluent) Diluent: 400 ppm AOAC hard water		
Soil load		5% fetal bovine serum		
Carrier type, # per lot		Stainless steel penicylinders, 60		
Test conditions	**Contact time**	10 mins	**Temp** 20.0°C	**RH** 48.4-54.7%
Neutralizer		Letheen broth + 0.1% sodium thiosulfate		
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		Testing on 4/17/18 resulted in carrier population control failure and thus was retested on 5/1/18. Relative humidity was only reported for inoculation of the carriers, not during the exposure treatment time. RH should be reported for the treatment time.		

14.	**MRID**	50847916	**Study Completion Date:**	05/21/18
Study Objective		Disinfectant		
Testing Lab; Lab Study ID		Accuratus Lab Services; A25299		
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		*Salmonella enterica* (ATCC 10708)		
Test Method		AOAC Use Dilution Method		
Application Method		Liquid		
Test Substance Preparation	**Name/ID**	Bio-Buster		
	Lots ☐ 1 ☐ 2 ☒ 3	BB-T016, BB-T017, BB-T018		
	Preparation	Tested concentration: LCL Dilution: 1.3 oz per gallon (0.93 g of test substance to 99.07 mL of diluent) Diluent: 400 ppm AOAC hard water		
Soil load		5% fetal bovine serum		

Carrier type, # per lot	Stainless steel penicylinders, 60					
Test conditions	**Contact time**	10 mins	**Temp**	20.0°C	**RH**	48.6-53.7%
Neutralizer	Letheen broth + 0.1% sodium thiosulfate					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)	Testing on 4/17/18 resulted in carrier population control failure and thus was retested on 4/30/18. Relative humidity was only reported for inoculation of the carriers, not during the exposure treatment time. RH should be reported for the treatment time.					

15.	**MRID**	50847917	**Study Completion Date:**	04/30/18
Study Objective		Disinfectant		
Testing Lab; Lab Study ID		Accuratus Lab Services; A25298		
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		*Staphylococcus aureus* (ATCC 6538)		
Test Method		AOAC Use Dilution Method		
Application Method		Liquid		
Test Substance Preparation	**Name/ID**	Bio-Buster		
	Lots ☐ 1 ☐ 2 ☒ 3	BB-T016, BB-T017, BB-T018		
	Preparation	Tested concentration: LCL Dilution: 1.3 oz per gallon (0.93 g of test substance to 99.07 mL of diluent) Diluent: 400 ppm AOAC hard water		
Soil load		5% fetal bovine serum		
Carrier type, # per lot		Stainless steel penicylinders, 60		
Test conditions		**Contact time** 10 min **Temp** 20.0-21.0°C **RH** 49.1-54%		
Neutralizer		Letheen broth + 0.1% sodium thiosulfate		
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		Relative humidity was only reported for inoculation of the carriers, not during the exposure treatment time. RH should be reported for the treatment time.		

16.	**MRID**	50847918	**Study Completion Date:**	06/18/18
Study Objective		Disinfectant		
Testing Lab; Lab Study ID		Accuratus Lab Services; A25534		
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		*Streptococcus suis* (ATCC 43765)		
Test Method		AOAC Use Dilution Method		
Application Method		Liquid		
Test Substance Preparation	**Name/ID**	Bio-Buster		
	Lots ☐ 1 ☒ 2 ☐ 3	BB-T016, BB-T017		
	Preparation	Tested concentration: LCL Dilution: 1.3 oz per gallon (2 g of test substance to 205.4 mL of diluent) Diluent: 400 ppm AOAC hard water		

Soil load	5% fetal bovine serum					
Carrier type, # per lot	Stainless steel penicylinders, 10					
Test conditions	**Contact time**	10 mins	**Temp**	20.0°C	**RH**	49.0-54.0%
Neutralizer	Letheen broth					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)	Relative humidity was only reported for inoculation of the carriers, not during the exposure treatment time. RH should be reported for the treatment time.					

17.	**MRID**	50847919	**Study Completion Date:**		06/26/18	
Study Objective		Disinfectant				
Testing Lab; Lab Study ID		Microbac Laboratories, Inc.; 962-107				
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		*Mycoplasma gallisepticum* (ATCC 15302)				
Test Method		AOAC Use Dilution Method				
Application Method		Liquid				
Test Substance Preparation	**Name/ID**	Bio-Buster				
	Lots ☐ 1 ☒ 2 ☐ 3	BB-T016, BB-T017				
	Preparation	Tested concentration: LCL Dilution: 1.3 oz per gallon (36.85 g of test substance to 3785 mL of diluent) Diluent: 400 ppm AOAC hard water				
Soil load		5% fetal bovine serum				
Carrier type, # per lot		Stainless steel penicylinders, 10				
Test conditions		**Contact time**	10 mins	**Temp**	20-21°C	**RH**	30-32%
Neutralizer		Mycoplasma broth				
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		N/A				

18.	**MRID**	50847920	**Study Completion Date:**	06/26/18
Study Objective		Disinfectant		
Testing Lab; Lab Study ID		Microbac Laboratories, Inc.; 962-104		
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		*Pectobacterium carotovorum* (ATCC 15713)		
Test Method		AOAC Use Dilution Method		
Application Method		Liquid		
Test Substance Preparation	**Name/ID**	Bio-Buster		
	Lots ☐ 1 ☒ 2 ☐ 3	BB-T016, BB-T017		
	Preparation	Tested concentration: LCL Dilution: 1.3 oz per gallon (36.85 g of test substance to 3785 mL of diluent) Diluent: 400 ppm AOAC hard water		

Soil load	5% fetal bovine serum					
Carrier type, # per lot	Stainless steel penicylinders, 10					
Test conditions	**Contact time**	10 mins	**Temp**	21°C	**RH**	56-57%
Neutralizer	Letheen broth					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)	N/A					

19.	**MRID**	50847921	**Study Completion Date:**			07/23/18
Study Objective		Disinfectant – virucidal				
Testing Lab, Lab Study ID		Eurofins Biolab S.R.L.; Study Plan: S-2018-00335 AM				
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		Pigeon adenovirus, strain IDA4 RVB-0146				
Indicator Cell Culture		TGE-R CCLV RIE 256 cells				
Test Method		Virucidal Hard Surface Efficacy Test				
Application Method		Liquid, 2.0 mL				
Test Substance Preparation	**Name/ID**	Bio-Buster				
	Lots ☐ 1 ☒ 2 ☐ 3	BB-T014, BB-T015				
	Preparation	Tested concentration: LCL Dilution: 1.3 oz per gallon (0.97 g of test substance per 99.03 mL of diluent) Diluent: AOAC hard water				
Soil load		5% FBS				
Carrier type, # per lot		1 glass petri dish carrier per batch				
Test conditions		**Contact time**	10 min	**Temp**	18-25°C	**RH** -
Neutralizer		PBS + filtration through S400 HR Columns Microspin				
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		ppm of $CaCO_3$ in hard water was not specified. Specific temperature during exposure was not reported. Relative humidity was not reported.				

20.	**MRID**	50847922	**Study Completion Date:**	05/31/18
Study Objective		Disinfectant		
Testing Lab; Lab Study ID		Microbac Laboratories, Inc.; 962-105		
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		*Haemophilus somnus* (ATCC 700026)		
Test Method		AOAC Use Dilution Method		
Application Method		Liquid		
Test Substance Preparation	**Name/ID**	Bio-Buster		
	Lots ☐ 1 ☒ 2 ☐ 3	BB-T016, BB-T017		
	Preparation	Tested concentration: LCL		

		Dilution: 1.3 oz per gallon (36.85 g of test substance to 3785 mL of diluent) Diluent: 400 ppm AOAC hard water				
Soil load		5% fetal bovine serum				
Carrier type, # per lot		Stainless steel penicylinders, 10				
Test conditions		**Contact time**	10 mins	**Temp**	20-21°C	**RH**	30-32%
Neutralizer		Letheen broth				
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		N/A				

21.	**MRID**	50847923	**Study Completion Date:**		07/31/18	
Study Objective		Disinfectant				
Testing Lab; Lab Study ID		Eurofins Biolab S.R.L.; Study Plan: S-2018-00334 AM				
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		*Vibrio anguillarum* (ATCC 43306)				
Test Method		AOAC Use Dilution Method				
Application Method		Liquid				
Test Substance Preparation	**Name/ID**	Bio-Buster				
	Lots **☐ 1 ☒ 2 ☐ 3**	BB-T014, BB-T015				
	Preparation	Tested concentration: LCL Dilution: 1.3 oz per gallon (0.97 g of test substance to 99.03 mL of diluent) Diluent: AOAC hard water				
Soil load		5% fetal bovine serum				
Carrier type, # per lot		Stainless steel penicylinders, 10				
Test conditions		**Contact time**	10 mins	**Temp**	20±1°C	**RH**	-
Neutralizer		Letheen broth				
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		ppm of $CaCO_3$ in hard water was not specified. Relative humidity was not reported.				

22.	**MRID**	50847924	**Study Completion Date:**		08/14/18	
Study Objective		Disinfectant – virucidal				
Testing Lab, Lab Study ID		Accuratus Lab Services; A25567				
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		Infectious Laryngotracheitis virus, Strain: LT-IVAX, obtained from Poutry Health and Specialties, St. Cloud, MN				
Indicator Cell Culture		CEK cells, Charles River				
Test Method		Virucidal Hard Surface Efficacy Test				
Application Method		Liquid, 2.0 mL				
Test Substance Preparation	**Name/ID**	Bio-Buster				
	Lots **☐ 1 ☒ 2 ☐ 3**	BB-T016, BB-T017				

	Preparation	Tested concentration: LCL Dilution: 1.3 oz per gallon (1 g of test substance per 102.69 mL of diluent) Diluent: 400 ppm AOAC hard water
Soil load		5% FBS
Carrier type, # per lot		1 glass petri dish carrier per batch
Test conditions		**Contact time** 10 min **Temp** 20.0°C **RH** 40%
Neutralizer		Sephadex Gel Filtration Column
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		Relative humidity was only reported for inoculation of the carriers, not during the exposure treatment time. RH should be reported for the treatment time.

IV STUDY RESULTS

Disinfection – Bactericidal Efficacy

MRID (Test Date)	Organism	No. Exhibiting Growth/Total No. Tested			Average CFU/Carrier (Average log_{10} per carrier)
		Batch BB-T016	Batch BB-T017	Batch BB-T018	
10 minute contact time, 400 ppm hard water, 5% soil load, 1.3 oz/gallon					
50847903	*Aeromonas hydrophila* (ATCC 19570)	0/10	0/10	-	6.5×10^4 (4.8)
50847906	*Listeria monocytogenes* (ATCC 984)	0/10	0/10	-	6.5×10^4 (4.8)
50847907	*Streptococcus pneumoniae* (ATCC 33400)	0/10	0/10	-	4.0×10^4 (4.6)
50847909	*Campylobacter jejuni* (ATCC 33560)	0/10	0/10	-	7.1×10^4 (4.9)
50847910	*Bordetella avium* (ATCC 35086)	0/10	0/10	-	(4.57 per 100 µL)
50847911	*Bordetella bronchiseptica* (ATCC 10580)	0/10	0/10	-	(5.37 per 100 µL)
50847912	*Escherichia coli* O157:H7 (ATCC 35150)	0/10	0/10	-	(4.73 per 100 µL)
50847914	*Xanthomonas campestris* (ATCC 11058)	0/10	0/10	-	(5.71 per 100 µL)

MRID (Test Date)	Organism	No. Exhibiting Growth/Total No. Tested			Average CFU/Carrier (Average log_{10} per carrier)
		Batch BB-T016	Batch BB-T017	Batch BB-T018	
50847915 (4/17/18)*	*Pseudomonas aeruginosa* (ATCC 15442)	1/60	-	-	(5.45 per 100 µL)
(5/1/18)		2/60	-	-	6.16 per 100 µL)
(4/18/18)		-	1/60	-	6.61 per 100 µL)
(4/19/18)		-	-	0/60	6.26 per 100 µL)
50847916 (4/17/18)*	*Salmonella enterica* (ATCC 10708)	0/60	1/60	0/60	(4.18 per 100 µL
(4/30/18)		0/60	0/60	0/60	(5.84 per 100 µL)
50847917 (4/18/18)	*Staphylococcus aureus* (ATCC 6538)	0/60	-	-	(6.29 per 100 µL)
(4/19/18)		-	2/60	-	(6.65per 100 µL)
(4/20/18)		-	-	0/60	(6.20 per 100 µL)
50847918	*Streptococcus suis* (ATCC 43765)	1° = 0 2° = 0	1° = 0 2° = 0	-	(5.43 per 100 µL)
50847919	*Mycoplasma gallisepticum* (ATCC 15302)	0/10	0/10	-	2.8×10^4 (4.5)
50847920	*Pectobacterium carotovorum* (ATCC 15713)	0/10	0/10	-	2.2×10^5 (5.3)
50847922	*Haemophilus somnus* (ATCC 700026)	0/10	0/10	-	5.7×10^4 (4.8)

*Invalid results – carrier control counts were too low.

MRID (Test Date)	Organism	No. Exhibiting Growth/Total No. Tested		Average log_{10} CFU/mL
		Batch BB-T014	Batch BB-T015	
10 minute contact time, AOAC hard water, 5% soil load, 1.3 oz/gallon				
50847923**	*Vibrio anguillarum* (ATCC 43306)	0/10	1/10	4.89

** Unknown water hardness.

Disinfection – Virucidal Efficacy

MRID	Organism	Description	Results				Dried Virus Control (Log_{10} $TCID_{50}$/carrier)	
			Lot BB-T016		Lot BB-T017			
		Replicate	*1*	*2*	*1*	*2*	*1*	*2*
50847904	Bovine Viral Diarrhea Virus, Strain: NADL (American	10^{-2} to 10^{-7} dilution	0/4	0/4	0/4	0/4	5.35	5.60

MRID	Organism	Description	Results		Dried Virus Control (Log_{10} $TCID_{50}$/carrier)
			Lot BB-T016	Lot BB-T017	
	BioResearch Laboratories)	Log_{10} $TCID_{50}$/carrier	≤1.10	≤1.10	
		Log Reduction	≥4.39		
10 minute contact time, 400 ppm AOAC Hard Water; 5% soil load					
50847905	Canine parvovirus, Strain: Cornell-780916-80, (ATCC VR-2017)	10^{-2} dilution	3/4	4/4	5.10
		10^{-3} to 10^{-7} dilution	0/4	0/4	
		Log_{10} $TCID_{50}$/carrier	≤1.85	≤2.10	
		Log Reduction	≥3.25	≥3.00	
50847908	Avian Influenza A (H5N1) virus, Strain VNH5N1- PR8/CDC-RG (CDC # 2006719965)	10^{-1} to 10^{-8} dilution	0/4	0/4	$10^{6.00}$ / 100 µL
		Log_{10} $TCID_{50}$/100µL	≤0.50	≤0.50	
		Log Reduction	≥5.50	≥5.50	
50847913	Feline Infectious Peritonitus virus, Strain FIPV-1146, P100 (ATCC VR-2202)	10^{-1} to 10^{-7} dilution	0/4	0/4	$10^{4.75}$ / 100 µL
		Log_{10} $TCID_{50}$/100µL	≤0.50	≤0.50	
		Log Reduction	≥4.25	≥4.25	
50847924	Infectious Laryngotracheitis virus, strain LT-IVAX (modified live vaccine (Poultry Health and Specialties, St. Cloud, MN)	10^{-1} to 10^{-6} dilution	0/4	0/4	$10^{4.50}$ / 100 µL
		Log_{10} $TCID_{50}$/100µL	≤0.50	≤0.50	
		Log Reduction	4.00	4.00	

Disinfection – Virucidal Efficacy

MRID	Organism	Description	Results	
			Lot BB-T014	Lot BB-T015
10 minute contact time, 5% soil load, AOAC hard water, 1.3 oz/gallon				
50847921**	Pidgeon adenovirus, Strain IDA4; RVB-0146	10^{-2} to 10^{-11} dilution	0/4	0/4
		Log_{10} $TCID_{50}$/100 µL	≤1.50	≤1.50
		Average Log_{10} $TCID_{50}$/100 µL	4.63	4.88
		Log Reduction	3.13	3.38

** Unknown water hardness.

V STUDY CONCLUSIONS

MRID	Claim	Surface Type	Application Method(s) and Dilution	Contact Time	Soil load	Diluent	Organism(s)	Data support tested conditions?
50847903 50847906 50847907 50847909 50847910 50847911 50847912 50847914 50847915 50847916 50847917 50847918 50847919 50847920 50847922	Disinfectant, bactericidal	Hard, non-porous surfaces	Liquid, 1.3 oz per gallon	10 minutes	5%	400 ppm AOAC hard water	• *Aeromonas hydrophila* (ATCC 19570) • *Listeria monocytogenes* (ATCC 984) • *Streptococcus pneumoniae* (ATCC 33400) • *Campylobacter jejuni* (ATCC 33560) • *Bordetella avium (ATCC 35088)* • *Bordetella bronchiseptica* (ATCC 10580) • *Escherichia coli O157:H7* (ATCC 35150) • *Xanthomonas campestris* (ATCC 11058) • *Pseudomonas aeruginosa* (ATCC 15442) • *Salmonella enterica* (ATCC 10708) • *Staphylococcus aureus* (ATCC 6538) • *Streptococcus suis* (ATCC 43765) • *Mycoplasma gallisepticum* (ATCC 15302) • *Pectobacterium carotovorum* (ATCC 15713) • *Haemophilus somnus* (ATCC 700026)	Yes

50847923	Disinfectant, bactericidal	Hard, non-porous surfaces	Liquid, 1.3 oz per gallon	10 minutes	5%	Unknown ppm of AOAC hard water	• *Vibrio anguillarum* (ATCC 43306)	**No,** failing data, unknown ppm of hard water, and unknown relative humidity.
50847904 50847905 50847908 50847913 50847924	Disinfectant, virucidal	Hard, non-porous surfaces	Liquid, 1.3 oz per gallon	10 minutes	5%	400 ppm AOAC hard water	• Bovine Viral Diarrhea Virus, Strain: NADL (American BioResearch Laboratories) • Canine parvovirus, Strain: Cornell-780916-80, (ATCC VR-2017) • Avian Influenza A (H5N1) virus, Strain VNH5N1-PR8/CDC-RG (CDC # 2006719965) • Feline Infectious Peritonitus virus, Strain FIPV-1146, P100 (ATCC VR-2202) • Infectious Laryngotracheitis virus, strain LT-IVAX (modified live vaccine (Poultry Health and Specialties, St. Cloud, MN)	**Yes**
50847921	Disinfectant, virucidal	Hard, non-porous surfaces	Liquid, 1.3 oz per gallon	10 minutes	5%	Unknown ppm of AOAC hard water	• Pidgeon adenovirus, Strain IDA4; RVB-0146	**No,** need ppm of hard water used, temperature during exposure time, and relative humidity. Unable to independently verify reported log reductions based on the information presented in the study.

VI LABEL COMMENTS (Label Date: 8/9/19)

1. The proposed label claims that the product, BioBuster, when diluted at 1.3 oz. per gallon of 400 ppm hard water, is an effective disinfectant against the following on hard, non-porous surfaces in the presence of 5% organic soil for a 10-minute contact time:

    - *Aeromonas hydrophila* (ATCC 19570)
    - *Listeria monocytogenes* (ATCC 984)
    - *Streptococcus pneumoniae* (ATCC 33400)
    - *Campylobacter jejuni* (ATCC 33560)
    - *Bordetella avium* (ATCC 35086)
    - *Bordetella bronchiseptica* (ATCC 10580)
    - *Escherichia coli O157:H7* (ATCC 35150)
    - *Xanthomonas campestris* (ATCC 11058)
    - *Pseudomonas aeruginosa* (ATCC 15442)
    - *Salmonella enterica* (ATCC 10708)
    - *Staphylococcus aureus* (ATCC 6538)
    - *Streptococcus suis* (ATCC 43765)
    - *Mycoplasma gallisepticum* (ATCC 15302)
    - *Pectobacterium carotovorum* (ATCC 15713)
    - *Haemophilus somnus* (ATCC 700026)
    - Bovine Viral Diarrhea Virus, Strain: NADL (American BioResearch Laboratories)
    - Canine parvovirus, Strain: Comell-780916-80, (ATCC VR-2017)
    - Avian Influenza A (H5N1) virus, Strain VNH5N1- PR8/CDC-RG (CDC # 2006719965)
    - Feline Infectious Peritonitus virus, Strain FIPV-1146, P100 (ATCC VR-2202)
    - Infectious Laryngotracheitis virus, strain LT-IVAX (modified live vaccine (Poultry Health and Specialties, St. Cloud, MN)

    These claims are **acceptable** as they are supported by the submitted data.

2. The proposed label claims that the product, BioBuster, when diluted at 1.3 oz. per gallon of 400 ppm hard watar, is **not** an effective disinfectant against the following on hard, non-porous surfaces in the presence of 5% organic soil for a 10-minuta contact time:

    - *Vibrio anguillarum* (ATCC 43306)

    These claims are **not acceptable.** All reference to this organism should be removed from the proposed label.

3. The proposed label claims that the product, BioBuster, when diluted at 1.3 oz. per gallon of 400 ppm hard water, is an effective disinfectant against the following on hard, non-porous surfaces in the presence of 5% organic soil for a 10-minute contact time:

    - Pidgeon adenovirus, Strain IDA4; RVB-0146

    These claims are **not acceptable.** Additional details are needed regarding the testing conditions (e.g. ppm of $CaCO_3$ in the diluent, specific temperature at time of exposure, ralative humidity at time of exposure) as well as information on the calculation of the virus titer and log reduction as these could not be verified based on the information presented in the report.

4. Make the following changes to the proposed label:
    a. Throughout the label, clarify surface claims with "hard nonporous".
    b. Throughout the label, qualify all "virus" or "virucidal" claims and alternate brand names with the viruses tested. This can be done in text or with a footnote.
    c. On page 1 of the label, remove the alternate brand names "BioBuster Aquatic Disinfectant and Virucide" and "BioBuster Air for Odor Control" as these names are misleading. The product was tested for application on hard, nonporous surfaces.
    d. On pages 4-5 of the label:
        i. All bacteria and virus claims should be specific to the organisms identified in number 1, including strains and ATCC numbers. For example, "Aeromonas spp." or "Adenovirus" are too broad as it implies efficacy against the entire genus.
        ii. Currently the agency's only allowance for reliance on viral hierarchy is for emerging viral pathogens (see web guidance). Therefore, reliance on the viral hierarchy to support label claims on page 4 is not acceptable. These claims should be removed from the label until the following conditions are met:
            1. Data should be submitted to the agency to support companion animal pests such as: canine adenovirus, canine coronavirus, feline rhinotracheitis, feline herpes, feline panleukopenia virus, canine parainfluenza virus, and canine distemper virus.
            2. As feline calicivirus is also an agency accepted surrogate for human norovirus, this virus is treated as a public health microbe and the applicant would need to provide supported efficacy data to the agency.
            3. Based on the OIE list, data is needed to support transmissible gastroenteritis, turkey rhinotracheitis, and infectious bronchitis.
            4. For all nonpublic health organisms not in the above categories, including nonpublic health plant pathogens, the applicant should have data on file to support each claim. This data does not have to be submitted at registration, but the agency reserves the right to request the data at any time.
    e. On page 5 of the label, remove "without concern of antimicrobial resistance" as this is not supported by the submitted data.
    f. On page 7 of the label,
        i. Revise the dilution table for 1% solution to specify a minimum of 0.325 ounces in 1 quart of water, as supported by the efficacy data.
        ii. Revise the dilution table for water system disinfectant to specify a minimum dilution rate of 1%. Data was not provided to support use of the product as a disinfectant at the 1:200 (0.5%) dilution or less.
        iii. Remove the claim that solutions are stable for 7 days as no data were submitted to support this claim. The solution should be replaced daily or more often if visibly soiled.
    g. On page 8 of the label,
        i. Continuous disinfection claim on page 8 would also need to similarly be revised to the 1% solution.
    h. On page 10 of the label,
        i. Revise "gross filth and heavy soil" to "visible soil" as a 5% soil load represents a visibly clean surface. Based on this, claims under "greenhouses and horticulture" to treat surfaces with a dilution of 1:50 "if

surfaces to be treated have not been precleaned" should also specify that surfaces should be visibly clean to start with. Again, any visible soil should be removed from surfaces prior to treatment.

ii. For evaporative coolers, specify that visibly soiled surfaces should be cleaned prior to treatment with product. Remove claim for treatment of cooler water with a 1:200 dilution. Product was not tested for efficacy in water.

Note to PM: The plant pathogens on page 5 should be checked to determine if RD would need to review data to support these organisms.

DATA PACKAGE BEAN SHEET

Date: 02-Jul-2019

Decision #: 551035
DP #: (453014)
PRIA
Parent DP #:
Submission #: 1034761
E-Sub #: 39226

* * * Registration Information * * *

Registration: 92589-R - BioBuster

Company: 92589 - ENVYSS, LLC

Risk Manager: RM 34 - Jacqueline Hardy - 703-308-6416 Room# PY1 S-8317

Risk Manager Reviewer: Lorena Rivas LRIVAS

Sent Date: PRIA Due Date: 06-Nov-2019 Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (A540) New end use product;FIFRA §2(mm) uses only;up to 25 public health organisms;

Ingredients: 013905, Sodium chloride(1.5%)

063604, Potassium peroxymonosulfate(21.41%)

* * * Data Package Information * * *

Expedite: ● Yes ○ No Date Sent: 28-Jun-2019 Due Back:

DP Ingredient: 013905, Sodium chloride

063604, Potassium peroxymonosulfate

DP Title: Efficacy

CSF Included: ● Yes ○ No Label Included: ● Yes ○ No Parent DP #:

Assigned To	Date In	Date Out	
Organization: AD / PSB			Last Possible Science Due Date: 07-Oct-2019
Team Name: EET			Science Due Date:
Reviewer Name:			Sub Data Package Due Date:
Contractor Name:			

* * * Studies Sent for Review * * *

Printed on Page 2

* * * Additional Data Package for this Decision * * *

Can be printed on its own page

* * * Data Package Instructions * * *

PRIA: New Hosptial Disinfectant
Electronic Submission - pls go to Documentum for Info

Technical Screen Due Date: August 1, 2019
Please review the efficacy data, MRID Nos 50847903-50847924, supporting hospital disinfection claim as well as claims agianst numerous animal viruses.

Date Evaluation
please review the submitted data to determine if its acceptable to support the claims on the proposed label.

50847903	Rahmat, R. (2018) Bio-Buster: AOAC Use Dilution Test: Aeromonas hydrophila: Final Report. Project Number: ENV/7A/12/08/17, 962/109. Unpublished study prepared by Microbac Laboratories. 26p.	810.2200/Disinfectants for Use on Environmental Surfaces, Guidance for Efficacy Testing	Not Reviewed (14-May-2019)
50847904	Chen, Z. (2018) Bio-Buster: Virucidal Hard-Surface Efficacy Test Bovine Viral Diarrhea Virus (Surrogate for Human Hepatitis C Virus): Final Report. Project Number: ENV/2C/12/06/17, 962/101. Unpublished study prepared by Microbac Laboratories. 30p.	810.2000/General Considerations for Testing Public Health Antimicrobial Pesticides, Guidance for Efficacy Testing	Not Reviewed (14-May-2019)
50847904	Chen, Z. (2018) Bio-Buster: Virucidal Hard-Surface Efficacy Test Bovine Viral Diarrhea Virus (Surrogate for Human Hepatitis C Virus): Final Report. Project Number: ENV/2C/12/06/17, 962/101. Unpublished study prepared by Microbac Laboratories. 30p.	810.2200/Disinfectants for Use on Environmentel Surfaces, Guidance for Efficacy Testing	Not Reviewed (14-May-2019)
50847905	Chen, Z. (2018) Bio-Buster: Virucidal Hard-Surface Efficacy Test: Final Report. Project Number: ENV/1D/12/06/17, 962/102. Unpublished study prepared by Microbac Laboratories. 31p.	810.2000/General Considerations for Testing Public Health Antimicrobial Pesticides, Guidance for Efficacy Testing	Not Reviewed (14-May-2019)
50847905	Chen, Z. (2018) Bio-Buster: Virucidal Hard-Surface Efficacy Test: Final Report. Project Number: ENV/1D/12/06/17, 962/102. Unpublished study prepared by Microbac Laboratories. 31p.	810.2200/Disinfectants for Use on Environmentel Surfaces, Guidance for Efficacy Testing	Not Reviewed (14-May-2019)
50847906	Rahmat, R. (2018) Bio-Buster: AOAC Use Dilution Test Listeria monocytogenes: Final Report. Project Number: ENV/4A/12/08/17, 962/106. Unpublished study prepared by Microbac Laboratories. 26p.	810.2000/General Considerations for Testing Public Health Antimicrobial Pesticides, Guidance for Efficacy Testing	Not Reviewed (14-May-2019)
50847906	Rahmat, R. (2018) Bio-Buster: AOAC Use Dilution Test Listeria monocytogenes: Final Report. Project Number: ENV/4A/12/08/17, 962/106. Unpublished study prepared by Microbac Laboratories. 26p.	810.2200/Disinfectants for Use on Environmentel Surfaces, Guidance for Efficacy Testing	Not Reviewed (14-May-2019)
50847907	Rahmat, R. (2018) Bio-Buster: AOAC Use Dilution Test Streptococcus pneumoniae: Final Report. Project Number: ENV/9A/12/08/17, 962/111. Unpublished study prepared by Microbac Laboratories. 27p.	810.2000/General Considerations for Testing Public Health Antimicrobial Pesticides, Guidance for Efficacy Testing	Not Reviewed (14-May-2019)
50847907	Rahmat, R. (2018) Bio-Buster: AOAC Use Dilution Test Streptococcus pneumoniae: Final Report. Project Number: ENV/9A/12/08/17, 962/111. Unpublished study prepared by Microbac Laboratories. 27p.	810.2200/Disinfectants for Use on Environmental Surfaces, Guidance for Efficacy Testing	Not Reviewed (14-May-2019)
50847908	Cantin, M. (2018) Bio-Buster: Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces: Avian Influenza A (H5N1) virus: Final Report. Project Number: ENV005121317/AFLU, A25565. Unpublished study prepared by Accuratus Lab Servicas. 29p.	810.2200/Disinfectants for Use on Environmental Surfaces, Guidance for Efficacy Testing	Not Reviewed (14-May-2019)
50847910	Sathe, M. (2018) Bio-Buster: AOAC Use-Dilution Method: Bordetella avium (ATCC 35086): Final Report. Project Number: ENV005121317/UD/4, A25531,. Unpublished study prepared by ACCURATUS LAB SERVICES. 30p.	810.2200/Disinfectants for Use on Environmentel Surfaces, Guidance for Efficacy Testing	Not Reviewed (14-May-2019)
50847911	Sathe, M. (2018) Bio-Buster: AOAC Use-Dilution Method: Bordatella bronchiseptica (ATCC 10580): Final Report. Project Number: ENV005121317/UD/5, A25532. Unpublished study prepared by Accuratus Lab Services. 30p.	810.2200/Disinfectants for Use on Environmental Surfaces, Guidance for Efficacy Testing	Not Reviewed (14-May-2019)

50847912	Sathe, M. (2018) Bio-Buster: AOAC Use-Dilution Method: Escherichia coli O157:H7 (ATCC 35150): Final Report. Project Number: ENV005121317/UD/6, A25533. Unpublished study prepared by Accuratus Lab Services. 30p.	810.2200/Disinfectants for Use on Environmental Surfaces, Guidance for Efficacy Testing	Not Reviewed (14-May-2019)
50847913	Cantin, M. (2018) Bio-Buster: Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces: Feline Infectious Peritonitis virus: Final Report. Project Number: ENV005121317/FIP, A25566. Unpublished study prepared by Accuratus Lab Services. 29p.	810.2200/Disinfectants for Use on Environmental Surfaces, Guidance for Efficacy Testing	Not Reviewed (14-May-2019)
50847914	Sathe, M. (2018) Bio-Buster: AOAC Use-Dilution Method: Xanthomonas campestris (ATCC 11058): Final Report. Project Number: ENV005121317/UD/8, A25530. Unpublished study prepared by Accuratus Lab Services. 30p.	810.2200/Disinfectants for Use on Environmental Surfaces, Guidance for Efficacy Testing	Not Reviewed (14-May-2019)
50847915	Sathe, M. (2018) Bio-Buster: AOAC Use-Dilution Method: Pseudomonas aeruginosa (ATCC 15442): Final Report. Project Number: ENV005121317/UD/1, A25297. Unpublished study prepared by Accuratus Lab Services. 34p.	810.2200/Disinfectants for Use on Environmental Surfaces, Guidance for Efficacy Testing	Not Reviewed (14-May-2019)
50847916	Sathe, M. (2018) Bio-Buster: AOAC Use-Dilution Method: Salmonella enterica (ATCC 10708): Final Report. Project Number: A25299, ENV005121317/UD/3. Unpublished study prepared by Accuratus Lab Services. 32p.	810.2200/Disinfectants for Use on Environmental Surfaces, Guidance for Efficacy Testing	Not Reviewed (14-May-2019)
50847917	Sathe, M. (2018) Bio-Buster: AOAC Use-Dilution Method: Staphylococcus aureus (ATC6538): Final Report. Project Number: ENV005121317/UD/2, A25298. Unpublished study prepared by Accuratus Lab Services. 32p.	810.2200/Disinfectants for Use on Environmental Surfaces, Guidance for Efficacy Testing	Not Reviewed (14-May-2019)
50847918	Sathe, M. (2018) Bio-Buster: AOAC Use-Dilution Method: Streptococcus sius (ATCC 43765): Final Report. Project Number: ENV005121317/UD/7, A25534. Unpublished study prepared by Accuratus Lab Services. 30p.	810.2200/Disinfectenta for Use on Environmental Surfaces, Guidance for Efficacy Testing	Not Reviewed (14-May-2019)
50847919	Rahmat, R. (2018) Bio-Buster: AOAC Use-Dilution Method: Mycoplasma gallisepticum: Final Report. Project Number: 962/107, ENV/5A/12/08/17. Unpublished study prepared by Microbac Laboratories. 28p.	810.2000/General Considerations for Testing Public Health Antimicrobial Pesticides, Guidance for Efficacy Testing	Not Reviewed (14-May-2019)
50847919	Rahmat, R. (2018) Bio-Buster: AOAC Use-Dilution Method: Mycoplasma gallisepticum: Final Report. Project Number: 962/107, ENV/5A/12/08/17. Unpublished study prepared by Microbec Laboratories. 28p.	810.2200/Disinfectants for Use on Environmental Surfaces, Guidance for Efficacy Testing	Not Reviewed (14-May-2019)
50847920	Rahmat, R. (2018) Bio-Buster: AOAC Use-Dilution Method: Pectobacterium carotovorum: Final Report. Project Number: ENV/2A/12/08/17, 962/104. Unpublished study prepared by Microbac Laboratories. 27p.	810.2000/General Considerations for Testing Public Health Antimicrobial Pesticides, Guidance for Efficacy Testing	Not Reviewed (14-May-2019)
50847920	Rahmat, R. (2018) Bio-Buster: AOAC Use-Dilution Method: Pectobacterium carotovorum: Final Report. Project Number: ENV/2A/12/08/17, 962/104. Unpublished study prepared by Microbac Laboratories. 27p.	810.2200/Disinfectants for Use on Environmentel Surfaces, Guidance for Efficacy Testing	Not Reviewed (14-May-2019)

DP#: (453014) *** Studies Sent for Review *** Decision#: (551035)

50847921		Brambilla, L. (2018) Virucidal Disinfectant Efficacy on Hard Non-Porous Surfaces Againstg Pigeon adenovirus on Bio-Buster: Final Report. Project Number: I97620170812/01, S/2018/00335/AM. Unpublished study prepared by Eurofins Biolab S.R.L. 20p.	810.2200/Disinfectants for Use on Environmental Surfaces, Guidance for Efficacy Testing	Not Reviewed (14-May-2019)
50847922		Rahmat, R. (2018) Bio-Buster: AOAC Use-Dilution Method: Haemophilus somnus: Final Report. Project Number: ENV/3A/12/08/17, 962/105. Unpublished study prepared by Microbac Laboratories. 26p.	810.2000/General Considerations for Testing Public Health Antimicrobial Pesticides, Guidance for Efficacy Testing	Not Reviewed (14-May-2019)
50847922		Rahmat, R. (2018) Bio-Buster: AOAC Use-Dilution Method: Haemophilus somnus: Final Report. Project Number: ENV/3A/12/08/17, 962/105. Unpublished study prepared by Microbec Laboratories. 26p.	810.2200/Disinfectants for Use on Environmental Surfaces, Guidance for Efficacy Testing	Not Reviewed (14-May-2019)
50847923		Brambilla, L. (2018) Evaluation of Bacterial Disinfectant Efficacy on Hard Non-Porous Surfaces Against Vibrio anguillarum on Bio-Buster: Final Report. Project Number: I97620170812/01, S/2018/00334/AM. Unpublished study prepared by Eurofins Biolab S.R.L. 22p.	810.2200/Disinfectants for Use on Environmental Surfaces, Guidance for Efficacy Testing	Not Reviewed (14-May-2019)
50847924		Cantin, M. (2018) Bio-Buster: Virucidal Efficacy of a Disinfectent for Use on Inanimate Environmental Surfaces: Infectious Laryngotracheitis virus: Final Report. Project Number: ENV005121317/ILGT, A25567. Unpublished study prepared by Accuratus Lab Services. 35p.	810.2200/Disinfectants for Use on Environmental Surfaces, Guidance for Efficacy Testing	Not Reviewed (14-May-2019)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

August 08, 2019

OPP Decision Number: 551035
EPA File Symbol No: 92589-R
Product Name: BioBuster
EPA Receipt Date: May 13, 2019
EPA Company Number: 92589
Company Name: ENVYSS, LLC

Dr. Connie B. Welch-DuJardin
Authorized Representative for Envyss, LLC
c/o ToXcel Toxicology & Regulatory Affairs
7140 Heritage Village Plaza
Gainesville, VA 20155-3061

Dear Dr. Welch-DuJardin:

The Agency has completed its preliminary technical screening of your application pursuant to Section 33(f)(4)(B)(i)(II) of the Federal Insecticide, Fungicide, and Rodenticide (FIFRA) Act, as amended by the Pesticide Registration Improvement Extension Act. The Agency has determined that your application have not passed the efficacy preliminary technical screen and therefore is subject to rejection if these applications are not corrected.

Specifically, the technical screen did not pass due to the Certificate of Analysis provide "stated and "estimated" the amounts for the active ingredients. *More information is needed on how the "estimated" values were determined.
Label provides Directions for Use as a sanitizer-Data is needed to support these claims.
Label claims against air borne pathogens-Efficacy data is needed to support such claims.
Label provides fogging/wet misting Use Directions-Data is needed to support eacb" dilution and temperature claim on the label.
Label provides Use Directions for water system disinfectant-Application needed to clarify whether the intent is to disinfect the tank or the water. If water, data is needed to support this type of claim. If the tank, then Use Directions must match disinfection rates and instructions need to be clarified.

In order to continue the review of the product, you will need to address the aforementioned data deficiencies within 10 business days of the date you received this letter. Corrections must be received by EPA by the 10th business day. EPA recommends sending your complete set of corrections by email to the contact listed below to ensure they are timely received. If studies or confidential information are being submitted by mail, a complete courtesy copy received by email by the deadline will be considered timely. If you cannot correct both applications or do not respond within 10 business days, your application will be rejected.

At this time, you could also choose to withdraw both your applications. If you have questions, please contact Lorena Rivas at 703-305-5027 or by email at rivas.lorena@epa.gov.

Sincerely,

Jacqueline Hardy

Jacqueline Hardy
Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510P)

Rivas, Lorena

From: Eronini, Lynette
Sent: Wednesday, September 04, 2019 5:14 PM
To: Rivas, Lorena
Cc: Hardy, Jacqueline; Hicks, Karen
Subject: 92589-R_D450313_BioBuster - TECHNICAL SCREEN - PASSED

From a chemistry point of view, the technical screen for 92589-R_D450313_BioBuster **passed**.

Note: Passing a technical screen is not indicative of a favorable chemistry review.

Lynette T. Umez-Eronini
Antimicrobials Division
Office of Pesticide Program
703-347-0132

Technical Screen

EPA Reg#/File Symbol: 92589-R	**E-Sub #**: 39226
DP Barcode: 453014	**Submission #**: 1034761
Product name: Biobuster	**Registrant**: Envyss, LLC
Reviewer's name: Thao Pham	**Risk Manager:** Lorena Rivas / Jacqueline Hardy
Completion due date: 8/1/19	**Completion Date**: 8/1/19

Formulation type: Liquid [] ; Towelettes []; Spray []; Solid [x]; Textile[]; Aerosol []; Other_____

Sterilant: []	Disinfectant: [x]	FC Sanitizer: []	NF Sanitizer []	TB: []	Fungicidal: []	Virucide: [x]

MRID(s): 50847903, 50847904, 50847905, 50847906, 50847907, 50847908, 50847909, 50847910, 50847911, 50847912, 50847913, 50847914, 50847915, 50847916, 50847917, 50847918, 50847919, 50847920, 50847921, 50847922, 50847923, 50847924

	Potassium Peroxymonosulfate	49.8% / 21.41%	48.3% / 20.8%
	Sodium Chloride	1.50%	1.43%

Label Claims: 1.3 oz per gallon for disinfection

BB-T014		Yes[]	No[]
BB-T015		Yes[]	No[]
BB-T016		Yes[]	No[]
BB-T017		Yes[]	No[]

Tested: **RTU[]** **Diluted** [x]	**Tested Dilution Rate:** Base orgs and canine parvo: 0.93 g per L Additional: 1.3 oz per gal
Certificate of Analysis: Yes[x] No[]	**Performed by testing Lab:** Yes[] No[x]

Test Lab: Microbac Laboratoies, Accuratus Lab Services, and Eurofins Biolab

Comments: Efficacy Review: Applicant is submitting data to support registration as a disinfectant.

The product has **failed** for the efficacy screen.

- Certificates of Analysis provide "stated" and "estimated" amounts for the active ingredients. More information is needed on how the "estimated" values were determined.
- Label provides directions for use as a sanitizer. Data is needed to support this claim.
- Label makes claims against air borne pathogens. Efficacy data is needed to support this claim.
- Label provides fogging / wet misting use directions. Data is needed to support each dilution and temperature claim on the label.
- Label provides use directions for water system disinfectant. Need applicant to clarify whether the intent is to disinfect the tank or the water. If water, data is needed to support this type of claim. If the tank, then use directions should match disinfection rates and instructions need to be clarified.

Note to PM: Label provides use directions for misting over poultry and swine.

50913900

toXcel

Toxicology & Regulatory Affairs
7140 Heritage Village Plaza
Gainesville, VA 20155-3061
USA

Phone: (703) 754-0248 **Fax: (703) 310-6950**

August 21, 2019
Jacqueline Hardy, PM 34
Registration Division (Mail Code 7510P)
US EPA / Office of Pesticide Programs
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Re: Response to Preliminary Technical Screen for Biobuster, EPA File Symbol 92589-R
EPA Company Number: 92589

Dear Ms. Hardy:

On behalf of our client, Envyss, LLC, we are hereby submitting our response to the Agency letter dated August 8, 2019 regarding the preliminary technical screen results for Biobuster, EPA File Symbol 92589-R. We have included in this response a statement from the laboratory, B.V. Bio-Corp PVT. LTD., clarifying the terms "estimated amount" and "stated amount" as noted on the Certificate of Analysis (COA). The "stated" amount refers to the current label claim and the "estimated" amount is an actual value based on the analytical method used for identifying the amount of active ingredient present in the product.

Regarding the need for additional efficacy data, we have revised the current draft proposed label where necessary therefore eliminating the need for additional data. Also, per your instructions, we made further clarifications to the use directions and disinfection rates accordingly.

Therefore, in response to the technical screen and in support of Biobuster (EPA File Symbol 92589-R) please find enclosed the following:

1. Registration Application (EPA Form 8570-1)
2. Transmittal Document
3. Data Matrix (EPA Form 8570-35) – Public and Private versions
4. Respect for Citation of Data
5. Revised label
6. Study data/analyses

If you have any other questions or require additional information, you may reach me by e-mail at Connie.Welch@toxcel.com or by phone at (703) 754-0248 x 8118.

Sincerely,

Dr. Connie B. Welch-DuJardin

Dr. Connie B. Welch-DuJardin
Vice President
Authorized Agent for Envyss, LLC

TRANSMITTAL DOCUMENT

1. **Name and Address of Submitter**

EnVyss, LLC
7140 Heritage Village Plaza
Gainesville, VA 20155

Authorized Representative
toXcel, LLC
7140 Heritage Village Plaza
Gainesville, VA 20155

2. **Regulatory Action**
Response to preliminary technical screening deficiency letter.
EPA Reg. No. 92589-R

3. **Transmittal Date**
21 August 2019

4. **List of Submitted Studies/Documents**

	Admin	· EPA Form 8570-1 – Application for Registration · EPA Form 8570-34 – Certification with Respect to Citation of Data · EPA Form 8570-35 – Data Matrix (Internal and Public) · Revised Label
MRID 50926201	**Volume 1**	Additional Information to Support the Certificate of Analysis in BioBuster's (EPA File Symbol 92589-R) Efficacy Studies; toXcel, LLC; 8 pages.

Company Name/Representative:

Company Name: EnVyss, LLC

Authorized Representative: Dr. Connie B. Welch

Dr. Connie B. Welch
toXcel LLC
7140 Heritage Village Plaza
Gainesville, VA 20155
Email: Connie.Welch@toxcel.com
Telephone: (703) 754-0248 x8118
Fax: (703) 310-6950

Date August 21, 2019

toXcel
Toxicology & Regulatory Affairs
7140 Heritage Village Plaza
Gainesville, VA 20155-3061
USA
Phone: (703) 754-0248 **Fax: (703) 310-6950**

May 13, 2019

Jacqueline Hardy, PM 34 (REGFEE)
Registration Division (Mail Code 7510P)
US EPA / Office of Pesticide Programs
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Re: Registration Application for BioBuster, EPA File Symbol 92589-R
EPA Company Number: 92589
PRIA Category: A540

Dear Ms. Hardy:

On behalf of our client, Envyss, LLC, we are submitting a new registration application for BioBuster, EPA File Symbol 92589-R. BioBuster is a broad-spectrum disinfectant and virucide.

The following are included with this registration application package:

1. Registration Application (EPA Form 8570-1)
2. PRIA Payment Confirmation
3. Transmittal Document
4. Confidential Statement of Formula (EPA Form 8570-4)
5. Data Matrix (EPA Form 8570-35) – Public and Private versions
6. Respect for Citation of Data
7. Study data

It is anticipated that this registration application will be categorized as a PRIA A540, with a corresponding review timeframe of 5 months. A small business application is being submitted separately in support of this application.

If you have any questions or require additional information, please contact me by e-mail at Connie.Welch@toxcel.com or by phone at (703) 754-0248 x 8118.

Sincerely,

Dr. Connie B. Welch-DuJardin
Vice President
Authorized Agent for Envyss, LLC

MRID: 50847900

TRANSMITTAL DOCUMENT

1. **Name and Address of Submitter**

Envyss, LLC
7140 Heritage Village Plaza
Gainesville, VA 20155

Authorized Representative
toXcel, LLC
7140 Heritage Village Plaza
Gainesville, VA 20155

2. **Regulatory Action**
Registration application for BioBuster.
EPA Reg. No. 92589-R

3. **Transmittal Date**
13 May 2019

4. **List of Submitted Studies/Documents**

	Admin	· EPA Form 8570-1 – Application for Registration · EPA Form 8570-34 – Certification with Respect to Citation of Data · EPA Form 8570-35 – Data Matrix (Internal and Public) · Confidential Statement of Formula (EPA Form 8570-4) · PRIA Payment Confirmation
MRID 50847901	**Volume 1**	BioBuster Group A Product Chemistry. May 10, 2019; toXcel, LLC; 830.1550, 830.1600, 830.1620, 830.1650, 830.1670, 830.1700, 830.1750, 830.1800 and 830.1900; 154 pages.
MRID 50847902	**Volume 2**	BioBuster Group B Product Chemistry. May 10, 2019; toXcel, LLC; 830.6302, 830.6303, 830.6304, 830.6313, 830.6314, 830.6315, 830.6316, 830.6317, 830.6319, 830.6320, 830.6321, 830.7000, 830.7100, 830.7200, 830.7220, 830.7300, 830.7370, 830.7550, 830.7840 and 830.7950; 24 pages.
MRID 50847903	**Volume 3**	AOAC Use Dilution Test – *Aeromonas hydrophila*; May 1, 2018; Microbac Laboratories, Inc.; Laboratory Project Identification Number 962-109; OPPTS 810.2200; 26 pages.
MRID 50847904	**Volume 4**	Virucidal Hard-Surface Efficacy Test – Bovine Viral Diarrhea Virus; April 18, 2018; Microbac Laboratories, Inc.; Laboratory Project Identification Number 962-101; OPPTS 810.2200; 30 pages.
MRID 50847905	**Volume 5**	Virucidal Hard-Surface Efficacy Test – Canine Parvovirus; April 30, 2018; Microbac Laboratories, Inc.; Laboratory Project Identification Number 962-102; OPPTS 810.2200; 31 pages.
MRID 50847906	**Volume 6**	AOAC Use Dilution Test – *Listeria monocytogenes*; May 1, 2018; Microbac Laboratories, Inc.; Laboratory Project Identification Number 962-106; OPPTS 810.2200; 26 pages.

MRID 50847907	**Volume 7**	AOAC Use Dilution Test – *Streptococcus pneumoniae*; May 1, 2018; Microbac Laboratories, Inc.; Laboratory Project Identification Number 962-111; OPPTS 810.2200; 27 pages.
MRID 50847908	**Volume 8**	Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces – Virus: Avian Influenza A (H5N1) virus; June 15, 2018; Accuratus Lab Services; Project Number A25565; OPPTS 810.2200; 29 pages.
MRID 50847909	**Volume 9**	AOAC Use Dilution Test – *Campylobacter jejuni*; May 9, 2018; Microbac Laboratories, Inc.; Laboratory Project Identification Number 962-103; OPPTS 810.2200; 27 pages.
MRID 50847910	**Volume 10**	AOAC Use-Dilution Method – *Bordetella avium* (ATCC 35086); June 18, 2018; Accuratus Lab Services; Project Number A25531; OPPTS 810.2200; 30 pages.
MRID 50847911	**Volume 11**	AOAC Use-Dilution Method – *Bordetella bronchiseptica* (ATCC 10580); June 18, 2018; Accuratus Lab Services; Project Number A25532; OPPTS 810.2200; 30 pages.
MRID 50847912	**Volume 12**	AOAC Use-Dilution Method – *Escherichia coli* O157:H7 (ATCC 35150); June 18, 2018; Accuratus Lab Services; Project Number A25533; OPPTS 810.2200; 30 pages.
MRID 50847913	**Volume 13**	Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces – Feline Infectious Peritonitis virus; June 14, 2018; Accuratus Lab Services; Project Number A25566; OPPTS 810.2200; 29 pages.
MRID 50847914	**Volume 14**	AOAC Use-Dilution Method – *Xanthomonas compestris* (ATCC 11058); June 18, 2018; Accuratus Lab Services; Project Number A25530; OPPTS 810.2200; 30 pages.
MRID 50847915	**Volume 15**	AOAC Use-Dilution Method – *Pseudomonas aeruginosa* (ATCC 15442); May 17, 2018; Accuratus Lab Services; Project Number A25297; OPPTS 810.2200; 34 pages.
MRID 50847916	**Volume 16**	AOAC Use-Dilution Method – *Salmonella enterica* (ATCC 10708); May 21, 2018; Accuratus Lab Services; Project Number A25299; OPPTS 810.2200; 32 pages.
MRID 50847917	**Volume 17**	AOAC Use-Dilution Method – *Staphylococcus aureus* (ATCC 6538); April 30, 2018; Accuratus Lab Services; Project Number A25298; OPPTS 810.2200; 32 pages.
MRID 50847918	**Volume 18**	AOAC Use-Dilution Method – *Streptococcus suis* (ATCC 43765); June 18, 2018; Accuratus Lab Services; Project Number A25534; OPPTS 810.2200; 30 pages.
MRID 50847919	**Volume 19**	AOAC Use Dilution Test – *Mycoplasma gallisepticum* (ATCC 15302); June 26, 2018; Microbac Laboratories, Inc.; Laboratory Project Identification Number 962-107; OPPTS 810.2200; 28 pages.
MRID 50847920	**Volume 20**	AOAC Use Dilution Test – *Pectobacterium carotovorum* (ATCC 15713); June 26, 2018; Microbac Laboratories, Inc.; Laboratory Project Identification Number 962-104; OPPTS 810.2200; 27 pages.
MRID 50847921	**Volume 21**	Virucidal Disinfectant Efficacy on Hard Non-Porous Surfaces Against Pigeon adenovirus on Bio-Buster; July 23, 2018; Eurofins – Biolab S.R.L.; Report No. S-2018-00335 AM; OPPTS 810.2200; 20 pages.
MRID 50847922	**Volume 22**	AOAC Use Dilution Test – *Heemophilus somnus*; May 31, 2018; Microbac Laboratories, Inc.; Laboratory Project Identification Number 962-105; OPPTS 810.2200; 26 pages.
MRID 50847923	**Volume 23**	Evaluation of Bactericidal Disinfectant Efficacy on Hard Non-Porous Surfaces Against *Vibrio anguillarum* on Bio-

MRID 50847924 **Volume 24**

Buster; July 31, 2018; Eurofins – Biolab S.R.L.; Report No. S-2018-00334 AM; OPPTS 810.2200; 22 pages.
Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces – Infectious Laryngotracheitis Virus; August 14, 2018; Accuratus Lab Services; Project No. A25567; OPPTS 810.2200; 35 pages.

Company Name/Representative:

Company Name: EnVyss, LLC

Authorized Representative: Dr. Connie B. Welch 13 May 2019
Dr. Connie B. Welch Date
toXcel LLC
7140 Heritage Village Plaza
Gainesville, VA 20155
Email: Connie.Welch@toxcel.com
Telephone: (703) 754-0248 x8118
Fax: (703) 310-6950

E-SUBMISSION
925 89-R
→Lorena

Memorandum

Date: 6 / 12 / 19

To: PM 34, **Regulatory Manager**

From: **Information Services Branch, ITRMD**

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a:
- ☒ **fully accepted submission**
- ☐ **partially accepted submission**
- ☐ **rejected submission**

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

September 04, 2019

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

TOXCEL, LLC
ENVYSS, LLC
7140 HERITAGE VILLAGE PLAZA
GAINESVILLE, VA 20155

Report of Analysis for Compliance with PR Notice 11-3

Thank you for your submittal of 21-AUG-19. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-3. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

June 03, 2019

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

TOXCEL, LLC
ENVYSS, LLC
7140 HERITAGE VILLAGE PLAZA
GAINESVILLE, VA 20155

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 13-MAY-19. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-03. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

34

PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 5/13/19

Experts In-Processing Signature: _____ Date 5/20/19 Fee Paid: Yes __

Division management contacted on issues No_____Yes _____Date _____

EPA Reg. Number: 92589-R	EPA Receipt Date: 5/13/19

	Items for Review			Yes	No	N/A*
1	**Application Form** (EPA Form 8570-1) signed & complete including package type			X		
2	**Confidential Statement of Formula** all boxes completed, form signed, and dated (EPA Form 8570-4)			X		
	a) All inerts, including fragrances, approved for the proposed uses (see Footnote A)	yes	no			
			X			
3	**Certification with Respect to Citation of Data** (EPA Form 8570-34) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	**Formulator's Exemption Statement** (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)					X
5	**Data Matrix** (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)			X		
		yes	no			
	a) Selective Method (Fee category experts use)	X				
	b) Cite-All (Fee category experts use)					
	c) Applicant owns all data (Fee category experts use)					
6	**5 Copies of Label (Electronic labels on CD are encouraged and guidance is available)**			X		
7	**Is the data package consistent with PR Notice 86-5**			X		
8	**Notice of Filing included with petitions**					X

9	**If applicable for conventional applications, <u>reduced risk rationale</u>**			
10	**<u>Required Data</u> and/or data waivers. See Footnote C.**			
	a) List study (or studies) not included with application			

Comments:

Documentation: PASS

↳ All required documents are complete.

Inert: Fail

↳ Inerts Not Approved see Inert Status Form Rejection letter on H:DRIVE

↳ Email sent to get updated information for Inerts.

11/3: PASS

↳ MRID: 508479

Status: Fail

↳ RF 6/4/19

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses or have an application pending with the Agency. If an unapproved inert with no application pending with the Agency is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses or have an application pending with the Agency **even if a product is currently registered** by consulting the inert Web site and if the inert is not approved nor has an application pending with the Agency, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient.** Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch.

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or

2. Provide the required information necessary to identify an inert approval application that is pending with the Agency; or

3. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

4. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R300 or R301), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or

2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or

2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

92589-R

E-SUBMISSION

Date sent to Lynette via email

Memorandum

Date: 9 / 17 / 19

To: PM34, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.

This is a:
- ☒ fully accepted submission
- ☐ partially accepted submission
- ☐ rejected submission

Stovall, Romadon

From:	Stovall, Romadon
Sent:	Tuesday, June 4, 2019 9:43 AM
To:	connie.Welch@toxcel.com
Subject:	Application for EPA Reg 92589-R Confidential
Attachments:	Inert Status 92589-R.doc

Dear Ms. DuJardin,

My name is Romadon Stovall and I am a contractor with the EPA. I am contacting you in regards to your submission in support of BioBuster (92589-R). We have found a deficiency with the submission that will need to be addressed:

1. Inerts listed on the Confidential Statement of Formula were not found in the agency database. Please see attached inert clearance form for additional information.

Please send directly to the PM. If you have any questions, please do not hesitate to contact me

Thanks,
Romadon Stovall

Contractor, US EPA
2777 S. Crystal Drive S-4824
Arlington, VA 22202
(703) 347-0527
Email: stovall.romadon@epa.gov

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Connie B.Welch-DuJardin
Toxcel- Toxicology & Regulatory Affairs
7140 Heritage Village Plaza
Gainesville, VA 20155-3061

RE: Application for Registration dated: 16-May-2019
Date Fee Payment: 08-May-2019
Product Name: BioBuster
EPA Registration Number: 92589-R
Decision Number: D-551035

Dear Registrant:

The Agency has completed its initial contents screen of your application pursuant to Section 33(f)(4)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended the Pesticide Registration Improvement Renewal Act. The Agency has determined that your application did not pass the initial contents screen and therefore must be rejected.

Specifically, the following items were missing or improperly formatted: Inerts associated with your submission were rejected.

In addition, in our attempts to clarify the above issue you failed to provide corrections in a timely manner.

Furthermore, pursuant to FIFRA Section 33(b)(2)(G) the Agency must retain 25% of the registration service fee. Any future submissions to the Agency will be considered a new application and subject to the full registration service fee and another initial contents screen of all necessary fees, forms, data, and draft labeling.

Sincerely,

XXXXXXXX, Director
Office of Pesticide Programs

A540 - New end use product.

- Must submit or reference Group A and B product chemistry, toxicity, and/or efficacy data for each proposed product.
- Data waivers may be requested. Chemistry data on the TGAI in addition to the EP is required if an unregistered source is used.

End Use (EP) or Manufacturing Use (MP) product or Technical Grade of the Active Ingredient (TGAI)

Guideline No.	Group A: Product Chemistry Data Study Title	EP Data Submitted	MP Data Submitted	TGAI Data Submitted
830.1550	Product Identity & Composition	X		
830.1600	Description of materials used to produce the product	X		
830.1650	Description of formulation process	X		
830.1670	Discussion on the formation of impurities	X		
830.1700	Preliminary analysis	X		
830.1750	Certified limits (158.345)	X		
830.1800	Enforcement analytical method	X		

Guideline No.	Group B: Product Chemistry Data Study Title	EP Data Submitted	MP Data Submitted	TGAI Data Submitted
830.6302	Color	X		
830.6303	Physical State	X		
830.6304	Odor	X		
830.6313	Stability to normal and elevated temperatures metal and metal ions			
830.6314	Oxidation/Reduction (Chemical incompatibility)	X		
830.6315	Flammability	X		
830.6316	Explodability	X		
830.6317	Storage stability*	X		
830.6319	Miscibility	X		
830.6320	Corrosion Characteristics*	X		
830.6321	Dielectric Breakdown Voltage	X		
830.7000	pH	X		
830.7050	UV/ Visible Absorption			
830.7100	Viscosity	X		
830.7200	Melting Point			
830.7220	Boiling Point			
830.7300	Density	X		
830.7370	Dissociation Constant			
830.7550	Partition Coefficient			
830.7840	Water Solubility			
830.7950	Vapor Pressure			

Grayed out = data not required *May not be included with initial application

A540 – Acute Toxicity Requirements

New products must either:
1) supply the product specific acute toxicity 6 pack data (listed below),
2) provide a bridging rationale document or waiver request or,
3) use the cite all method of data compensation, if applicable. The bridging document directs OPP to use a currently registered set of 6 acute toxicity data and label; instead of submitting product specific data.

Guideline No.	Acute toxicity (6 pack) Study Title	Cite All	Selective	Waiver Request	Bridging Rational
830.1100	Acute Oral (LD50)		✓		
830.1200	Acute Dermal (LD50)		X		
830.1300	Acute Inhalation (LC50)		X		
830.2400	Acute Eye Irritation		X		
830.2500	Acute Dermal Irritation		X		
830.2600	Dermal Sensitization		X		

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

May 16, 2019

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OPP Decision Number: D-551035
EPA File Symbol or Registration Number: 92589-R
Product Name: BioBuster
EPA Receipt Date: 13-May-2019
EPA Company Number: 92589
Company Name: ENVYSS, LLC

CONNIE WELCH-DUJARDIN
TOXCEL, LLC
ENVYSS, LLC
7140 HERITAGE VILLAGE PLAZA
GAINESVILLE, VA 20155-

SUBJECT: Receipt of Application and 75% Small Business Waiver Request

Dear Registrant:

The Office of Pesticide Programs has received your application, 75% small business waiver request, and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: A540

New end use product;FIFRA §2(mm) uses only;up to 25 public health organisms;

Your request for waiver has been forwarded for review. You will be notified in writing when a determination is made regarding your request. If your waiver request is approved, the decision review time period will start on the date of approval. If your waiver request is denied, you will receive an invoice for the outstanding balance.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-8154.

Sincerely,

Front End Processing Staff
Information Technology & Resources Management Division

Fee for Service {1034761E~

This package includes the following

- ○ New Registration
- ○ Amendment

☑ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ___

for Division

- ◉ AD
- ○ BPPD
- ○ RD

Risk Mgr. 34

Receipt No. S- 1034761

EPA File Symbol/Reg. No. 92589-R

Pin-Punch Date: 5/13/2019

☐ This item is NOT subject to FFS action.

Action Code:

Requested: A540

Granted: A540

Amount Due: $ _____

Parent/Child Decisions:

DOCUMENTUM

▣ Inert Cleared for Intended Use ▣ Uncleared Inert in Product

Reviewer: M. Alavi Date: 05/16/19

Remarks:

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DATA MATRIX

Date: August 21, 2019	EPA Reg No./ File Symbol **92589-R**	Page 1 of 12
Applicant's/Registrant's Name and Address: **Envyss, LLC**	Product: **BioBuster**	

Ingredient: **Potassium peroxymonosulfate (PC 63604) Sodium Chloride (PC 13905)**

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
PRODUCT CHEMISTRY:					
TGAI – Sodium Chloride					
830.1550 (40 CFR §158.155)	Product Identity and Composition	50847901	Envyss, LLC	OWN	
830.1600 (40 CFR §158.160)	Description of Materials Used to Produce the Product	50847901	Envyss, LLC	OWN	
830.1650 (40 CFR §158.165)	Description of Formulation Process	50847901	Envyss, LLC	OWN	
830.1670 (40 CFR §158.167)	Discussion of Formation of Impurities	50847901	Envyss, LLC	OWN	
830.1700 (40 CFR §158.170)	Preliminary Analysis	50847901	Envyss, LLC	OWN	
830.1750 (40 CFR §158.175)	Certification of Limits	50847901	Envyss, LLC	OWN	
830.1800 (40 CFR §158.180)	Analytical Methods to Verify Certified Limits	50847901	Envyss, LLC	OWN	
830.1900 (64-1)	Submittal of Samples	Upon Request	Envyss, LLC	OWN	
830.6302 (63-2)	Color	50847902	Envyss, LLC	OWN	
830.6303 (63-3)	Physical State	50847902	Envyss, LLC	OWN	
830.6304 (63-4)	Odor	50847902	Envyss, LLC	OWN	

Signature	Name and Title	Date
Dr. Connie B. Welch-DuJardin	Dr. Connie B. Welch-DuJardin	Aug. 21, 2019

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DATA MATRIX

Date: August 21, 2019	EPA Reg No./ File Symbol **92589-R**	Page 2 of 12
Applicant's/Registrant's Name and Address: **Envyss, LLC**	Product: **BioBuster**	

Ingredient: **Potassium peroxymonosulfate (PC 63604) Sodium Chloride (PC 13905)**

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7200 (63-5)	Melting Point	50847902	Envyss, LLC	OWN	
830.7220 (63-6)	Boiling Point	50847902	Envyss, LLC	OWN	
830.7300 (63-7)	Density, Bulk Density or Specific Gravity	50847902	Envyss, LLC	OWN	
830.7840 (63-8)	Water Solubility: Column Elution Method; Shake Flask Method	50847902	Envyss, LLC	OWN	
830.7950 (63-9)	Vapor Pressure	50847902	Envyss, LLC	OWN	
830.7370 (63-10)	Dissociation Constant	50847902	Envyss, LLC	OWN	
830.7550; 830.7560; 830.7570 (63-11)	Octanol-Water Partition Coefficient	50847902	Envyss, LLC	OWN	
830.7000 (63-12)	pH	50847902	Envyss, LLC	OWN	
830.6313 (63-13)	Stability to temperature, metals, and metal ions	50847902	Envyss, LLC	OWN	
830.6314 (63-14)	Oxidizing or Reducing Action	50847902	Envyss, LLC	OWN	
830.6315 (63-15)	Flammability	50847902	Envyss, LLC	OWN	
830.6316 (63-16)	Explodability	50847902	Envyss, LLC	OWN	
830.6317 (63-17)	Storage Stability	50847902	Envyss, LLC	OWN	

Signature Dr. Connie B. Welch-DuJardin	Name and Title Dr. Connie B. Welch-DuJardin	Date Aug. 21, 2019

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DATA MATRIX

Date: August 21, 2019	EPA Reg No./ File Symbol **92589-R**	Page 3 of 12
Applicant's/Registrant's Name and Address: **Envyss, LLC**	Product: **BioBuster**	

Ingredient: **Potassium peroxymonosulfate (PC 63604) Sodium Chloride (PC 13905)**

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6319 (63-19)	Miscibility	50847902	Envyss, LLC	OWN	
830.6320 (63-20)	Corrosion Characteristics	50847902	Envyss LLC	OWN	
830.6321 (63-21)	Dielectric Breakdown Voltage	50847902	Envyss, LLC	OWN	
TGAI – Potassium Peroxymonosulfate					
830.1550 (40 CFR §158.155)	Product Identity and Composition	50847901	Envyss, LLC	OWN	
830.1600 (40 CFR §158.160)	Description of Materials Used to Produce the Product	50847901	Envyss, LLC	OWN	
830.1650 (40 CFR §158.165)	Description of Formulation Process	50847901	Envyss, LLC	OWN	
830.1670 (40 CFR §158.167)	Discussion of Formation of Impurities	50847901	Envyss, LLC	OWN	
830.1700 (40 CFR §158.170)	Preliminary Analysis	50847901	Envyss, LLC	OWN	
830.1750 (40 CFR §158.175)	Certification of Limits	50847901	Envyss, LLC	OWN	
830.1800 (40 CFR §158.180)	Analytical Methods to Verify Certified Limits	50847901	Envyss, LLC	OWN	
830.1900 (64-1)	Submittal of Samples	Upon Request	Envyss, LLC	OWN	

Signature Dr. Connie B. Welch-DuJardin	Name and Title Dr. Connie B. Welch-DuJardin	Date Aug. 21, 2019

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DATA MATRIX

Date: August 21, 2019	EPA Reg No./ File Symbol **92589-R**	Page 4 of 12
Applicant's/Registrant's Name and Address: **Envyss, LLC**	Product: **BioBuster**	

Ingredient: **Potassium peroxymonosulfate (PC 63604) Sodium Chloride (PC 13905)**

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6302 (63-2)	Color	50847902	Envyss, LLC	OWN	
830.6303 (63-3)	Physical State	50847902	Envyss, LLC	OWN	
830.6304 (63-4)	Odor	50847902	Envyss, LLC	OWN	
830.7200 (63-5)	Melting Point	50847902	Envyss, LLC	OWN	
830.7220 (63-6)	Boiling Point	50847902	Envyss, LLC	OWN	
830.7300 (63-7)	Density, Bulk Density or Specific Gravity	50847902	Envyss, LLC	OWN	
830.7840 (63-8)	Water Solubility: Column Elution Method; Shake Flask Method	50847902	Envyss, LLC	OWN	
830.7950 (63-9)	Vapor Pressure	50847902	Envyss, LLC	OWN	
830.7370 (63-10)	Dissociation Constant	50847902	Envyss, LLC	OWN	
830.7550; 830.7560; 830.7570 (63-11)	Octanol-Water Partition Coefficient	50847902	Envyss, LLC	OWN	
830.7000 (63-12)	pH	50847902	Envyss, LLC	OWN	
830.6313 (63-13)	Stability to temperature, metals, and metal ions	50847902	Envyss, LLC	OWN	
830.6314 (63-14)	Oxidizing or Reducing Action	50847902	Envyss, LLC	OWN	

Signature Dr. Connie B. Welch-DuJardin	Name and Title Dr. Connie B. Welch-DuJardin	Date Aug. 21, 2019

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DATA MATRIX

Date: August 21, 2019	EPA Reg No./ File Symbol **92589-R**	Page 5 of 12
Applicant's/Registrant's Name and Address: **Envyss, LLC**	Product: **BioBuster**	

Ingredient: **Potassium peroxymonosulfate (PC 63604) Sodium Chloride (PC 13905)**

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6315 (63-15)	Flammability	50847902	Envyss, LLC	OWN	
830.6316 (63-16)	Explodability	50847902	Envyss, LLC	OWN	
830.6317 (63-17)	Storage Stability	50847902	Envyss, LLC	OWN	
830.6319 (63-19)	Miscibility	50847902	Envyss, LLC	OWN	
830.6320 (63-20)	Corrosion Characteristics	50847902	Envyss, LLC	OWN	
830.6321 (63-21)	Dielectric Breakdown Voltage	50847902	Envyss, LLC	OWN	
EP- BioBuster					
830.1550 (40 CFR §158.155)	Product Identity and Composition	50847901	Envyss, LLC	OWN	
830.1600 (40 CFR §158.160)	Description of Materials Used to Produce the Product	50847901	Envyss, LLC	OWN	
830.1650 (40 CFR §158.165)	Description of Formulation Process	50847901	Envyss, LLC	OWN	
830.1670 (40 CFR §158.167)	Discussion of Formation of Impurities	50847901	Envyss, LLC	OWN	
830.1700 (40 CFR §158.170)	Preliminary Analysis	50847901	Envyss, LLC	OWN	
830.1750 (40 CFR §158.175)	Certification of Limits	50847901	Envyss, LLC	OWN	

Signature	Name and Title	Date
Dr. Connie B. Welch-DuJardin	Dr. Connie B. Welch-DuJardin	Aug. 21, 2019

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Date: August 21, 2019	EPA Reg No./ File Symbol **92589-R**	Page 6 of 12
Applicant's/Registrant's Name and Address: **Envyss, LLC**	Product: **BioBuster**	

Ingredient: **Potassium peroxymonosulfate (PC 63604) Sodium Chloride (PC 13905)**

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1800 (40 CFR §158.180)	Analytical Methods to Verify Certified Limits	50847901	Envyss, LLC	OWN	
830.1900 (64-1)	Submittal of Samples	Upon Request	Envyss, LLC	OWN	
830.6302 (63-2)	Color	50847902	Envyss, LLC	OWN	
830.6303 (63-3)	Physical State	50847902	Envyss, LLC	OWN	
830.6304 (63-4)	Odor	50847902	Envyss, LLC	OWN	
830.7300 (63-7)	Density, Bulk Density or Specific Gravity	50847902	Envyss, LLC	OWN	
830.7840 (63-8)	Water Solubility: Column Elution Method; Shake Flask Method	50847902	Envyss, LLC	OWN	
830.7950 (63-9)	Vapor Pressure	50847902	Envyss, LLC	OWN	
830.7370 (63-10)	Dissociation Constant	50847902	Envyss, LLC	OWN	
830.7550; 830.7560; 830.7570 (63-11)	Octanol-Water Partition Coefficient	50847902	Envyss, LLC	OWN	
830.7000 (63-12)	pH	50847902	Envyss, LLC	OWN	
830.7100 (63-18)	Viscosity	50847902	Envyss, LLC	OWN	
830.6313 (63-13)	Stability to temperature, metals, and metal ions	50847902	Envyss, LLC	OWN	

Signature Dr. Connie B. Welch-DuJardin	Name and Title Dr. Connie B. Welch-DuJardin	Date Aug. 21, 2019

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DATA MATRIX

Date: August 21, 2019	EPA Reg No./ File Symbol **92589-R**	Page 7 of 12
Applicant's/Registrant's Name and Address: **Envyss, LLC**	Product: **BioBuster**	

Ingredient: **Potassium peroxymonosulfate (PC 63604) Sodium Chloride (PC 13905)**

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6314 (63-14)	Oxidizing or Reducing Action	50847902	Envyss, LLC	OWN	
830.6315 (63-15)	Flammability	50847902	Envyss, LLC	OWN	
830.6316 (63-16)	Explodability	50847902	Envyss, LLC	OWN	
830.6317 (63-17)	Storage Stability	50847902	Envyss, LLC	OWN	
830.6319 (63-19)	Miscibility	50847902	Envyss, LLC	OWN	
830.6320 (63-20)	Corrosion Characteristics	50847902	Envyss, LLC	OWN	
830.6321 (63-21)	Dielectric Breakdown Voltage	50847902	Envyss, LLC	OWN	
TOXICITY:					
TGAI – Sodium Chloride					
870.1100 (81-1)	Acute Oral Toxicity: Rat		Envyss, LLC	PL	Page 7 of 1993 Inorganic Halides RED
870.1200 (81-2)	Acute Dermal Toxicity: Rat		Envyss, LLC	PL	Page 7 of 1993 Inorganic Halides RED
870.1300 (81-3)	Acute Inhalation Toxicity: Rat		Envyss, LLC	PL	Page 7 of 1993 Inorganic Halides RED

Signature	Name and Title	Date
Dr. Connie B. Welch-DuJardin	Dr. Connie B. Welch-DuJardin	Aug. 21, 2019

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DATA MATRIX

Date: August 21, 2019	EPA Reg No./ File Symbol **92589-R**	Page 8 of 12
Applicant's/Registrant's Name and Address: **Envyss, LLC**	Product: **BioBuster**	

Ingredient: **Potassium peroxymonosulfate (PC 63604) Sodium Chloride (PC 13905)**

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.2400 (81-4)	Primary Eye Irritation: Rabbit		Envyss, LLC	PL	Page 7 of 1993 Inorganic Halides RED
870.2500 (81-5)	Primary Dermal Irritation		Envyss, LLC	PL	Page 7 of 1993 Inorganic Halides RED
870.2600 (81-6)	Dermal Sensitization		Envyss, LLC	PL	Page 7 of 1993 Inorganic Halides RED
TGAI – Potassium Peroxymonosulfate					
870.1100 (81-1)	Acute Oral Toxicity: Rat	42607401	A. H. Robins Company Inc.	OLD	
870.1200 (81-2)	Acute Dermal Toxicity: Rat	42607402	A. H. Robins Company Inc.	OLD	
870.1300 (81-3)	Acute Inhalation Toxicity: Rat	42591201	A. H. Robins Company Inc.	OLD	
870.2400 (81-4)	Primary Eye Irritation: Rabbit	42607403	A. H. Robins Company Inc.	OLD	
870.2500 (81-5)	Primary Dermal Irritation	42607404	A. H. Robins Company Inc.	OLD	

Signature Dr. Connie B. Welch-DuJardin	Name and Title Dr. Connie B. Welch-DuJardin	Date Aug. 21, 2019

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DATA MATRIX

Date: August 21, 2019	EPA Reg No./ File Symbol **92589-R**	Page 9 of 12
Applicant's/Registrant's Name and Address: **Envyss, LLC**	Product: **BioBuster**	

Ingredient: **Potassium peroxymonosulfate (PC 63604) Sodium Chloride (PC 13905)**

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.2600 (81-6)	Dermal Sensitization	42607405	A. H. Robins Company Inc.	OLD	Waived – RED (PMN)
870.3700 (83-3)	Teratogenicity - two species (TGAI)				Waived – RED (PMN)
870.3800 (83-4)	Reproduction, 2-generation (TGAI)				Waived – RED (PMN)
870.5265 (84-2)	Mutagenicity: Gene Mutation (Ames) (TGAI)				Waived – RED (PMN)
870.5395 (84-2)	Mutagenicity: Structural Chromosome Aberration (Micronucleus Assay) (TGAI)				Waived – RED (PMN)
EP- Biobuster					
870.1100 (81-1)	Acute Oral Toxicity: Rat	41057402	A. H. Robins Company Inc.	OLD	
870.1200 (81-2)	Acute Dermal Toxicity: Rat	41057403	A. H. Robins Company Inc.	OLD	
870.1300 (81-3)	Acute Inhalation Toxicity: Rat	41057404	A. H. Robins Company Inc.	OLD	
870.2400 (81-4)	Primary Eye Irritation: Rabbit	41057405 41057406	A. H. Robins Company Inc.	OLD	
870.2500 (81-5)	Primary Dermal Irritation	41057407, 41057408	A. H. Robins Company Inc.	OLD	
870.2600 (81-6)	Dermal Sensitization	41057409	A. H. Robins Company Inc.	OLD	

Signature	Name and Title	Date
Dr. Connie B. Welch-DuJardin	Dr. Connie B. Welch-DuJardin	Aug. 21, 2019

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DATA MATRIX

Date: August 21, 2019	EPA Reg No./ File Symbol **92589-R**	Page 10 of 12
Applicant's/Registrant's Name and Address: **Envyss, LLC**	Product: **BioBuster**	

Ingredient: **Potassium peroxymonosulfate (PC 63604) Sodium Chloride (PC 13905)**

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
EFFICACY:					
EP - Biobuster					
810.2200	AOAC Use Dilution Test – *Aeromonas hydrophila*	50847903	Envyss, LLC	OWN	
810.2200	Virucidal Hard-Surface Efficacy Test – Bovine Viral Diarrhea Virus	50847904	Envyss, LLC	OWN	
810.2200	Virucidal Hard-Surface Efficacy Test – Canine Parvovirus	50847905	Envyss, LLC	OWN	
810.2200	AOAC Use Dilution Test – *Listeria monocytogenes*	50847906	Envyss, LLC	OWN	
810.2200	AOAC Use Dilution Test – *Streptococcus pneumoniae*	50847907	Envyss, LLC	OWN	
810.2200	Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces – Virus: Avian Influenza A (H5N1) virus	50847908	Envyss, LLC	OWN	
810.2200	AOAC Use Dilution Test – *Campylobacter jejuni*	50847909	Envyss, LLC	OWN	
810.2200	AOAC Use-Dilution Method – *Bordetella avium*	50847910	Envyss, LLC	OWN	
810.2200	AOAC Use-Dilution Method – *Bordetella bronchiseptica*	50847911	Envyss, LLC	OWN	
810.2200	AOAC Use-Dilution Method – *Escherichia coli*	50847912	Envyss, LLC	OWN	
810.2200	Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces	50847913	Envyss, LLC	OWN	

Signature Dr. Connie B. Welch-DuJardin	Name and Title Dr. Connie B. Welch-DuJardin	Date Aug. 21, 2019

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DATA MATRIX

Date: August 21, 2019	EPA Reg No./ File Symbol **92589-R**	Page 11 of 12
Applicant's/Registrant's Name and Address: **Envyss, LLC**	Product: **BioBuster**	

Ingredient: **Potassium peroxymonosulfate (PC 63604) Sodium Chloride (PC 13905)**

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	– Feline Infectious Peritonitis virus				
810.2200	AOAC Use-Dilution Method – *Xanthomonas compestris*	50847914	Envyss, LLC	OWN	
810.2200	AOAC Use-Dilution Method – *Pseudomonas aeruginosa*	50847915	Envyss, LLC	OWN	
810.2200	AOAC Use-Dilution Method – *Salmonella enterica*	50847916	Envyss, LLC	OWN	
810.2200	AOAC Use-Dilution Method – *Staphylococcus aureus*	50847917	Envyss, LLC	OWN	
810.2200	AOAC Use-Dilution Method – *Streptococcus suis*	50847918	Envyss, LLC	OWN	
810.2200	AOAC Use-Dilution Method – *Mycoplasma galisepticum*	50847919	Envyss, LLC	OWN	
810.2200	AOAC Use-Dilution Method – *Pectobacterium carotovorum*	50847920	Envyss, LLC	OWN	
810.2200	Virucidal Hard-Surface Efficacy Test – Pigeon adenovirus	50847921	Envyss, LLC	OWN	
810.2200	AOAC Use-Dilution Method – *Haemophilus somnus*	50847922	Envyss, LLC	OWN	
810.2200	Bacterialcidal Hard-Surface Efficacy Test – *Vibrio anguillarum*	50847923	Envyss, LLC	OWN	
810.2200	Virucidal Hard-Surface Efficacy Test – Infectious Laryngotracheitis Virus	50847924	Envyss, LLC	OWN	
NON-GUIDELINE:					

Signature	Name and Title	Date
Dr. Connie B. Welch-DuJardin	Dr. Connie B. Welch-DuJardin	Aug. 21, 2019

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Date: August 21, 2019	EPA Reg No./ File Symbol **92589-R**	Page 12 of 12
Applicant's/Registrant's Name and Address: **Envyss, LLC**	Product: **BioBuster**	

Ingredient: **Potassium peroxymonosulfate (PC 63604) Sodium Chloride (PC 13905)**

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Additional information for COA	509250	Envyss, LLC	OWN	Volume 1

Signature	Name and Title	Date
Dr. Connie B. Welch-DuJardin	Dr. Connie B. Welch-DuJardin	Aug. 21, 2019

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DATA MATRIX

Date: August 21, 2019	EPA Reg No./ File Symbol **92589-R**	Page 1 of 12
Applicant's/Registrant's Name and Address: **Envyss, LLC**	Product: **BioBuster**	

Ingredient: **Potassium peroxymonosulfate (PC 63604) Sodium Chloride (PC 13905)**

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
PRODUCT CHEMISTRY:					
TGAI – Sodium Chloride					
830.1550 (40 CFR §158.155)	Product Identity and Composition	50847901	Envyss, LLC	OWN	
830.1600 (40 CFR §158.160)	Description of Materials Used to Produce the Product	50847901	Envyss, LLC	OWN	
830.1650 (40 CFR §158.165)	Description of Formulation Process	50847901	Envyss, LLC	OWN	
830.1670 (40 CFR §158.167)	Discussion of Formation of Impurities	50847901	Envyss, LLC	OWN	
830.1700 (40 CFR §158.170)	Preliminary Analysis	50847901	Envyss, LLC	OWN	
830.1750 (40 CFR §158.175)	Certification of Limits	50847901	Envyss, LLC	OWN	
830.1800 (40 CFR §158.180)	Analytical Methods to Verify Certified Limits	50847901	Envyss, LLC	OWN	
830.1900 (64-1)	Submittal of Samples	Upon Request	Envyss, LLC	OWN	
830.6302 (63-2)	Color	50847902	Envyss, LLC	OWN	
830.6303 (63-3)	Physical State	50847902	Envyss, LLC	OWN	
830.6304 (63-4)	Odor	50847902	Envyss, LLC	OWN	

Signature	Name and Title	Date
Dr. Connie B. Welch-DuJardin	Dr. Connie B. Welch-DuJardin	Aug. 21, 2019

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DATA MATRIX

Date: August 21, 2019	EPA Reg No./ File Symbol **92589-R**	Page 2 of 12
Applicant's/Registrant's Name and Address: **Envyss, LLC**	Product: **BioBuster**	

Ingredient: **Potassium peroxymonosulfate (PC 63604) Sodium Chloride (PC 13905)**

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7200 (63-5)	Melting Point	50847902	Envyss, LLC	OWN	
830.7220 (63-6)	Boiling Point	50847902	Envyss, LLC	OWN	
830.7300 (63-7)	Density, Bulk Density or Specific Gravity	50847902	Envyss, LLC	OWN	
830.7840 (63-8)	Water Solubility: Column Elution Method; Shake Flask Method	50847902	Envyss, LLC	OWN	
830.7950 (63-9)	Vapor Pressure	50847902	Envyss, LLC	OWN	
830.7370 (63-10)	Dissociation Constant	50847902	Envyss, LLC	OWN	
830.7550; 830.7560; 830.7570 (63-11)	Octanol-Water Partition Coefficient	50847902	Envyss, LLC	OWN	
830.7000 (63-12)	pH	50847902	Envyss, LLC	OWN	
830.6313 (63-13)	Stability to temperature, metals, and metal ions	50847902	Envyss, LLC	OWN	
830.6314 (63-14)	Oxidizing or Reducing Action	50847902	Envyss, LLC	OWN	
830.6315 (63-15)	Flammability	50847902	Envyss, LLC	OWN	
830.6316 (63-16)	Explodability	50847902	Envyss, LLC	OWN	
830.6317 (63-17)	Storage Stability	50847902	Envyss, LLC	OWN	

Signature Dr. Connie B. Welch-DuJardin	Name and Title Dr. Connie B. Welch-DuJardin	Date Aug. 21, 2019

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Date: August 21, 2019	EPA Reg No./ File Symbol **92589-R**	Page 3 of 12
Applicant's/Registrant's Name and Address: **Envyss, LLC**	Product: **BioBuster**	

Ingredient: **Potassium peroxymonosulfate (PC 63604) Sodium Chloride (PC 13905)**

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6319 (63-19)	Miscibility	50847902	Envyss, LLC	OWN	
830.6320 (63-20)	Corrosion Characteristics	50847902	Envyss LLC	OWN	
830.6321 (63-21)	Dielectric Breakdown Voltage	50847902	Envyss, LLC	OWN	
TGAI – Potassium Peroxymonosulfate					
830.1550 (40 CFR §158.155)	Product Identity and Composition	50847901	Envyss, LLC	OWN	
830.1600 (40 CFR §158.160)	Description of Materials Used to Produce the Product	50847901	Envyss, LLC	OWN	
830.1650 (40 CFR §158.165)	Description of Formulation Process	50847901	Envyss, LLC	OWN	
830.1670 (40 CFR §158.167)	Discussion of Formation of Impurities	50847901	Envyss, LLC	OWN	
830.1700 (40 CFR §158.170)	Preliminary Analysis	50847901	Envyss, LLC	OWN	
830.1750 (40 CFR §158.175)	Certification of Limits	50847901	Envyss, LLC	OWN	
830.1800 (40 CFR §158.180)	Analytical Methods to Verify Certified Limits	50847901	Envyss, LLC	OWN	
830.1900 (64-1)	Submittal of Samples	Upon Request	Envyss, LLC	OWN	

Signature	Name and Title	Date
Dr. Connie B. Welch-DuJardin	Dr. Connie B. Welch-DuJardin	Aug. 21, 2019

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DATA MATRIX

Date: August 21, 2019	EPA Reg No./ File Symbol **92589-R**	Page 4 of 12
Applicant's/Registrant's Name and Address: **Envyss, LLC**	Product: **BioBuster**	

Ingredient: **Potassium peroxymonosulfate (PC 63604) Sodium Chloride (PC 13905)**

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6302 (63-2)	Color	50847902	Envyss, LLC	OWN	
830.6303 (63-3)	Physical State	50847902	Envyss, LLC	OWN	
830.6304 (63-4)	Odor	50847902	Envyss, LLC	OWN	
830.7200 (63-5)	Melting Point	50847902	Envyss, LLC	OWN	
830.7220 (63-6)	Boiling Point	50847902	Envyss, LLC	OWN	
830.7300 (63-7)	Density, Bulk Density or Specific Gravity	50847902	Envyss, LLC	OWN	
830.7840 (63-8)	Water Solubility: Column Elution Method; Shake Flask Method	50847902	Envyss, LLC	OWN	
830.7950 (63-9)	Vapor Pressure	50847902	Envyss, LLC	OWN	
830.7370 (63-10)	Dissociation Constant	50847902	Envyss, LLC	OWN	
830.7550; 830.7560; 830.7570 (63-11)	Octanol-Water Partition Coefficient	50847902	Envyss, LLC	OWN	
830.7000 (63-12)	pH	50847902	Envyss, LLC	OWN	
830.6313 (63-13)	Stability to temperature, metals, and metal ions	50847902	Envyss, LLC	OWN	
830.6314 (63-14)	Oxidizing or Reducing Action	50847902	Envyss, LLC	OWN	

Signature Dr. Connie B. Welch-DuJardin	Name and Title Dr. Connie B. Welch-DuJardin	Date Aug. 21, 2019

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DATA MATRIX

Date: August 21, 2019	EPA Reg No./ File Symbol **92589-R**	Page 5 of 12
Applicant's/Registrant's Name and Address: **Envyss, LLC**	Product: **BioBuster**	

Ingredient: **Potassium peroxymonosulfate (PC 63604) Sodium Chloride (PC 13905)**

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6315 (63-15)	Flammability	50847902	Envyss, LLC	OWN	
830.6316 (63-16)	Explodability	50847902	Envyss, LLC	OWN	
830.6317 (63-17)	Storage Stability	50847902	Envyss, LLC	OWN	
830.6319 (63-19)	Miscibility	50847902	Envyss, LLC	OWN	
830.6320 (63-20)	Corrosion Characteristics	50847902	Envyss, LLC	OWN	
830.6321 (63-21)	Dielectric Breakdown Voltage	50847902	Envyss, LLC	OWN	
EP- BioBuster					
830.1550 (40 CFR §158.155)	Product Identity and Composition	50847901	Envyss, LLC	OWN	
830.1600 (40 CFR §158.160)	Description of Materials Used to Produce the Product	50847901	Envyss, LLC	OWN	
830.1650 (40 CFR §158.165)	Description of Formulation Process	50847901	Envyss, LLC	OWN	
830.1670 (40 CFR §158.167)	Discussion of Formation of Impurities	50847901	Envyss, LLC	OWN	
830.1700 (40 CFR §158.170)	Preliminary Analysis	50847901	Envyss, LLC	OWN	
830.1750 (40 CFR §158.175)	Certification of Limits	50847901	Envyss, LLC	OWN	

Signature Dr. Connie B. Welch-DuJardin	Name and Title Dr. Connie B. Welch-DuJardin	Date Aug. 21, 2019

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DATA MATRIX

Date: August 21, 2019	EPA Reg No./ File Symbol **92589-R**	Page 6 of 12
Applicant's/Registrant's Name and Address: **Envyss, LLC**	Product: **BioBuster**	

Ingredient: **Potassium peroxymonosulfate (PC 63604) Sodium Chloride (PC 13905)**

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1800 (40 CFR §158.180)	Analytical Methods to Verify Certified Limits	50847901	Envyss, LLC	OWN	
830.1900 (64-1)	Submittal of Samples	Upon Request	Envyss, LLC	OWN	
830.6302 (63-2)	Color	50847902	Envyss, LLC	OWN	
830.6303 (63-3)	Physical State	50847902	Envyss, LLC	OWN	
830.6304 (63-4)	Odor	50847902	Envyss, LLC	OWN	
830.7300 (63-7)	Density, Bulk Density or Specific Gravity	50847902	Envyss, LLC	OWN	
830.7840 (63-8)	Water Solubility: Column Elution Method; Shake Flask Method	50847902	Envyss, LLC	OWN	
830.7950 (63-9)	Vapor Pressure	50847902	Envyss, LLC	OWN	
830.7370 (63-10)	Dissociation Constant	50847902	Envyss, LLC	OWN	
830.7550; 830.7560; 830.7570 (63-11)	Octanol-Water Partition Coefficient	50847902	Envyss, LLC	OWN	
830.7000 (63-12)	pH	50847902	Envyss, LLC	OWN	
830.7100 (63-18)	Viscosity	50847902	Envyss, LLC	OWN	
830.6313 (63-13)	Stability to temperature, metals, and metal ions	50847902	Envyss, LLC	OWN	

Signature	Name and Title	Date
Dr. Connie B. Welch-DuJardin	Dr. Connie B. Welch-DuJardin	Aug. 21, 2019

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DATA MATRIX

Date: August 21, 2019	EPA Reg No./ File Symbol **92589-R**	Page 8 of 12
Applicant's/Registrant's Name and Address: **Envyss, LLC**	Product: **BioBuster**	

Ingredient: **Potassium peroxymonosulfate (PC 63604) Sodium Chloride (PC 13905)**

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.2400 (81-4)	Primary Eye Irritation: Rabbit		Envyss, LLC	PL	Page 7 of 1993 Inorganic Halides RED
870.2500 (81-5)	Primary Dermal Irritation		Envyss, LLC	PL	Page 7 of 1993 Inorganic Halides RED
870.2600 (81-6)	Dermal Sensitization		Envyss, LLC	PL	Page 7 of 1993 Inorganic Halides RED
TGAI – Potassium Peroxymonosulfate					
870.1100 (81-1)	Acute Oral Toxicity: Rat	42607401	A. H. Robins Company Inc.	OLD	
870.1200 (81-2)	Acute Dermal Toxicity: Rat	42607402	A. H. Robins Company Inc.	OLD	
870.1300 (81-3)	Acute Inhalation Toxicity: Rat	42591201	A. H. Robins Company Inc.	OLD	
870.2400 (81-4)	Primary Eye Irritation: Rabbit	42607403	A. H. Robins Company Inc.	OLD	
870.2500 (81-5)	Primary Dermal Irritation	42607404	A. H. Robins Company Inc.	OLD	

Signature Dr. Connie B. Welch-DuJardin	Name and Title Dr. Connie B. Welch-DuJardin	Date Aug. 21, 2019

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Applicant's/Registrant's Name and Address: **Envyss, LLC**	Product: **BioBuster**	

Ingredient: **Potassium peroxymonosulfate (PC 63604) Sodium Chloride (PC 13905)**

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6314 (63-14)	Oxidizing or Reducing Action	50847902	Envyss, LLC	OWN	
830.6315 (63-15)	Flammability	50847902	Envyss, LLC	OWN	
830.6316 (63-16)	Explodability	50847902	Envyss, LLC	OWN	
830.6317 (63-17)	Storage Stability	50847902	Envyss, LLC	OWN	
830.6319 (63-19)	Miscibility	50847902	Envyss, LLC	OWN	
830.6320 (63-20)	Corrosion Characteristics	50847902	Envyss, LLC	OWN	
830.6321 (63-21)	Dielectric Breakdown Voltage	50847902	Envyss, LLC	OWN	
TOXICITY:					
TGAI – Sodium Chloride					
870.1100 (81-1)	Acute Oral Toxicity: Rat		Envyss, LLC	PL	Page 7 of 1993 Inorganic Halides RED
870.1200 (81-2)	Acute Dermal Toxicity: Rat		Envyss, LLC	PL	Page 7 of 1993 Inorganic Halides RED
870.1300 (81-3)	Acute Inhalation Toxicity: Rat		Envyss, LLC	PL	Page 7 of 1993 Inorganic Halides RED

Signature	Name and Title	Date
Dr. Connie B. Welch-DuJardin	Dr. Connie B. Welch-DuJardin	Aug. 21, 2019

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DATA MATRIX

Date: August 21, 2019	EPA Reg No./ File Symbol **92589-R**	Page 9 of 12
Applicant's/Registrant's Name and Address: **Envyss, LLC**	Product: **BioBuster**	

Ingredient: **Potassium peroxymonosulfate (PC 63604) Sodium Chloride (PC 13905)**

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.2600 (81-6)	Dermal Sensitization	42607405	A. H. Robins Company Inc.	OLD	Waived – RED (PMN)
870.3700 (83-3)	Teratogenicity - two species (TGAI)				Waived – RED (PMN)
870.3800 (83-4)	Reproduction, 2-generation (TGAI)				Waived – RED (PMN)
870.5265 (84-2)	Mutagenicity: Gene Mutation (Ames) (TGAI)				Waived – RED (PMN)
870.5395 (84-2)	Mutagenicity: Structural Chromosome Aberration (Micronucleus Assay) (TGAI)				Waived – RED (PMN)
EP- Biobuster					
870.1100 (81-1)	Acute Oral Toxicity: Rat	41057402	A. H. Robins Company Inc.	OLD	
870.1200 (81-2)	Acute Dermal Toxicity: Rat	41057403	A. H. Robins Company Inc.	OLD	
870.1300 (81-3)	Acute Inhalation Toxicity: Rat	41057404	A. H. Robins Company Inc.	OLD	
870.2400 (81-4)	Primary Eye Irritation: Rabbit	41057405 41057406	A. H. Robins Company Inc.	OLD	
870.2500 (81-5)	Primary Dermal Irritation	41057407, 41057408	A. H. Robins Company Inc.	OLD	
870.2600 (81-6)	Dermal Sensitization	41057409	A. H. Robins Company Inc.	OLD	

Signature	Name and Title	Date
Dr. Connie B. Welch-DuJardin	Dr. Connie B. Welch-DuJardin	Aug. 21, 2019

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

DATA MATRIX

Date: August 21, 2019	EPA Reg No./ File Symbol **92589-R**	Page 10 of 12
Applicant's/Registrant's Name and Address: **Envyss, LLC**	Product: **BioBuster**	

Ingredient: **Potassium peroxymonosulfate (PC 63604) Sodium Chloride (PC 13905)**

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
EFFICACY:					
EP - Biobuster					
810.2200	AOAC Use Dilution Test – *Aeromonas hydrophila*	50847903	Envyss, LLC	OWN	
810.2200	Virucidal Hard-Surface Efficacy Test – Bovine Viral Diarrhea Virus	50847904	Envyss, LLC	OWN	
810.2200	Virucidal Hard-Surface Efficacy Test – Canine Parvovirus	50847905	Envyss, LLC	OWN	
810.2200	AOAC Use Dilution Test – *Listeria monocytogenes*	50847906	Envyss, LLC	OWN	
810.2200	AOAC Use Dilution Test – *Streptococcus pneumoniae*	50847907	Envyss, LLC	OWN	
810.2200	Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces – Virus: Avian Influenza A (H5N1) virus	50847908	Envyss, LLC	OWN	
810.2200	AOAC Use Dilution Test – *Campylobacter jejuni*	50847909	Envyss, LLC	OWN	
810.2200	AOAC Use-Dilution Method – *Bordetella avium*	50847910	Envyss, LLC	OWN	
810.2200	AOAC Use-Dilution Method – *Bordetella bronchiseptica*	50847911	Envyss, LLC	OWN	
810.2200	AOAC Use-Dilution Method – *Escherichia coli*	50847912	Envyss, LLC	OWN	
810.2200	Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces	50847913	Envyss, LLC	OWN	

Signature Dr. Connie B. Welch-DuJardin	Name and Title Dr. Connie B. Welch-DuJardin	Date Aug. 21, 2019

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

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Form Approved OMB No. 2070-0060

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DATA MATRIX

Date: August 21, 2019	EPA Reg No./ File Symbol **92589-R**	Page 11 of 12
Applicant's/Registrant's Name and Address: **Envyss, LLC**	Product: **BioBuster**	

Ingredient: **Potassium peroxymonosulfate (PC 63604) Sodium Chloride (PC 13905)**

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	– Feline Infectious Peritonitis virus				
810.2200	AOAC Use-Dilution Method – *Xanthomonas compestris*	50847914	Envyss, LLC	OWN	
810.2200	AOAC Use-Dilution Method – *Pseudomonas aeruginosa*	50847915	Envyss, LLC	OWN	
810.2200	AOAC Use-Dilution Method – *Salmonella enterica*	50847916	Envyss, LLC	OWN	
810.2200	AOAC Use-Dilution Method – *Staphylococcus aureus*	50847917	Envyss, LLC	OWN	
810.2200	AOAC Use-Dilution Method – *Streptococcus suis*	50847918	Envyss, LLC	OWN	
810.2200	AOAC Use-Dilution Method – *Mycoplasma galisepticum*	50847919	Envyss, LLC	OWN	
810.2200	AOAC Use-Dilution Method – *Pectobacterium carotovorum*	50847920	Envyss, LLC	OWN	
810.2200	Virucidal Hard-Surface Efficacy Test – Pigeon adenovirus	50847921	Envyss, LLC	OWN	
810.2200	AOAC Use-Dilution Method – *Haemophilus somnus*	50847922	Envyss, LLC	OWN	
810.2200	Bacterialcidal Hard-Surface Efficacy Test – *Vibrio anguillarum*	50847923	Envyss, LLC	OWN	
810.2200	Virucidal Hard-Surface Efficacy Test – Infectious Laryngotracheitis Virus	50847924	Envyss, LLC	OWN	
NON-GUIDELINE:					

Signature	Name and Title	Date
Dr. Connie B. Welch-DuJardin	Dr. Connie B. Welch-DuJardin	Aug. 21, 2019

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date: August 21, 2019	EPA Reg No./ File Symbol **92589-R**	Page 12 of 12
Applicant's/Registrant's Name and Address: **Envyss, LLC**	Product: **BioBuster**	

Ingredient: **Potassium peroxymonosulfate (PC 63604) Sodium Chloride (PC 13905)**

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Additional information for COA	509262-01	Envyss, LLC	OWN	Volume 1

Signature	Name and Title	Date
Dr. Connie B. Welch-DuJardin	Dr. Connie B. Welch-DuJardin	Aug. 21, 2019

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

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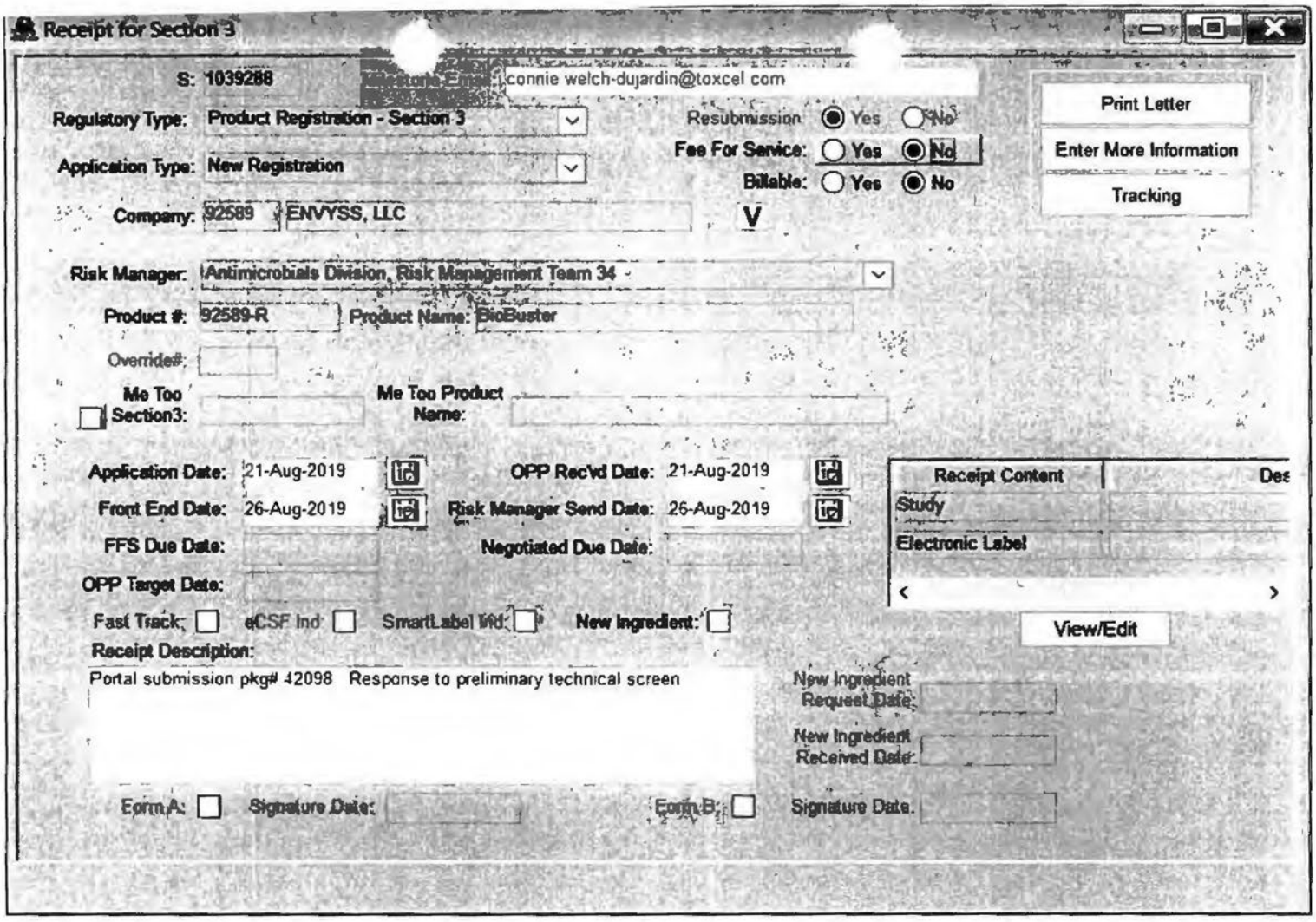
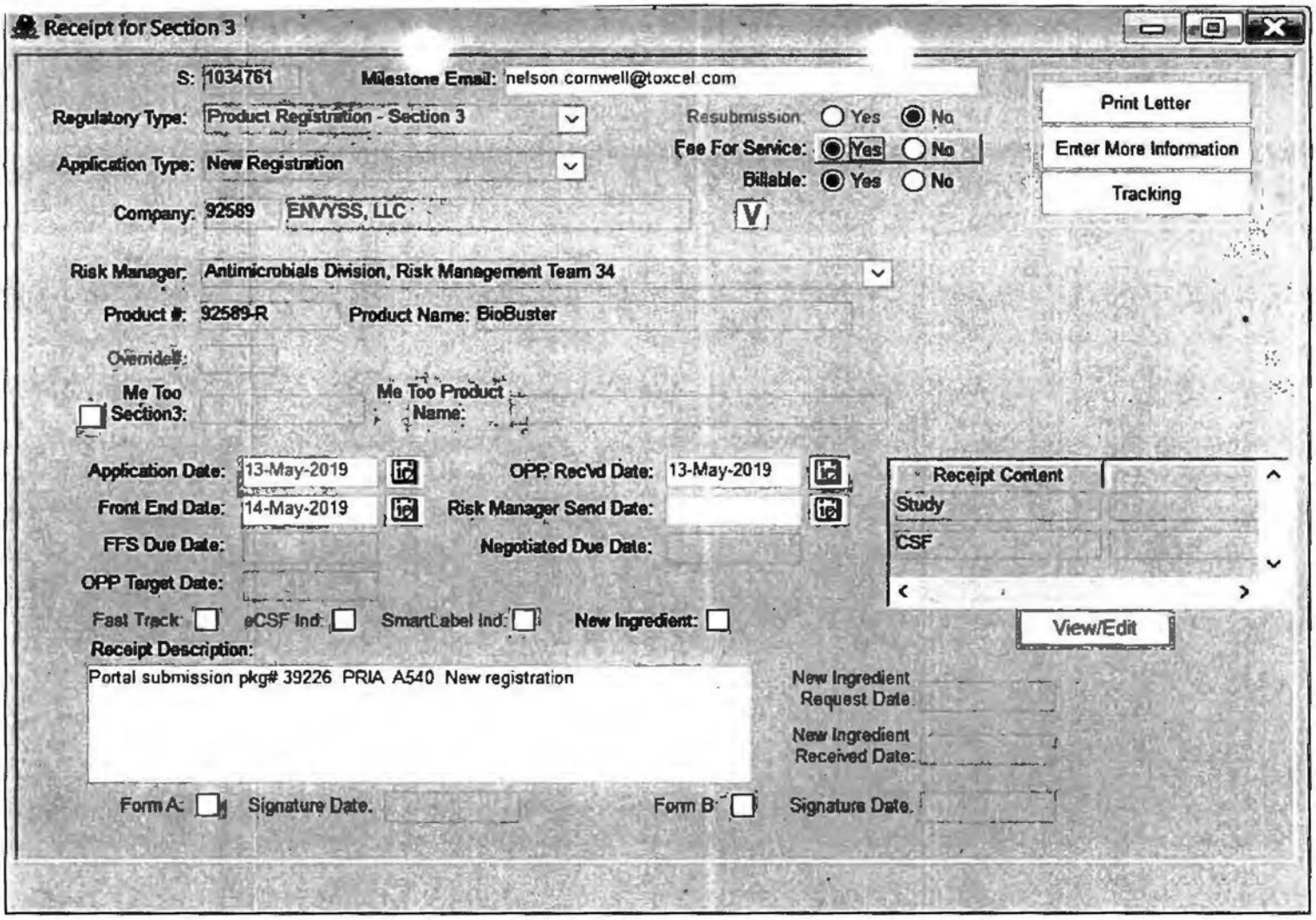

Receipt for Section 3
S: 1039288
connie welch-dujardin@toxcel com
Regulatory Type: Product Registration - Section 3
Application Type: New Registration
Company: 92589 ENVYSS, LLC
Resubmission Yes No
Fee For Service: Yes No
Billable: Yes No
Print Letter
Enter More Information
Tracking
Risk Manager: Antimicrobials Division, Risk Management Team 34
Product #: 92589-R
Product Name: BioBuster
Override#:
Me Too Section3:
Me Too Product Name:
Application Date: 21-Aug-2019
Front End Date: 26-Aug-2019
FFS Due Date:
OPP Target Date:
OPP Rec'vd Date: 21-Aug-2019
Risk Manager Send Date: 26-Aug-2019
Negotiated Due Date:
Receipt Content
Study
Electronic Label
View/Edit
Fast Track:
eCSF Ind:
SmartLabel Ind:
New Ingredient:
Receipt Description:
Portal submission pkg# 42098 Response to preliminary technical screen
New Ingredient Request Date:
New Ingredient Received Date:
Form A:
Signature Date:
Form B:
Signature Date:


Receipt for Section 3
S: 1034761
Milestone Email: nelson.cornwell@toxcel.com
Regulatory Type: Product Registration - Section 3
Resubmission: Yes No
Fee For Service: Yes No
Billable: Yes No
Application Type: New Registration
Company: 92589 ENVYSS, LLC
Print Letter
Enter More Information
Tracking
Risk Manager: Antimicrobials Division, Risk Management Team 34
Product #: 92589-R
Product Name: BioBuster
Override:
Me Too Section3:
Me Too Product Name:
Application Date: 13-May-2019
OPP Rec'vd Date: 13-May-2019
Front End Date: 14-May-2019
Risk Manager Send Date:
FFS Due Date:
Negotiated Due Date:
OPP Target Date:
Receipt Content
Study
CSF
Fast Track:
eCSF Ind:
SmartLabel Ind:
New Ingredient:
View/Edit
Receipt Description:
Portal submission pkg# 39226 PRIA A540 New registration
New Ingredient Request Date:
New Ingredient Received Date:
Form A:
Signature Date:
Form B:
Signature Date:

Djapao, Banza

From: notification@pay.gov
Sent: Wednesday, May 08, 2019 1:10 PM
To: Connie Welch
Subject: Pay.gov Payment Confirmation: PRIA Service Fees


An official email of the United States government

Your payment has been submitted to Pay.gov and the details are below. If you have any questions regarding this payment, please contact Michael Yanchulis at (703) 347-0237 or yanchulis.michael@epa.gov.

Application Name: PRIA Service Fees
Pay.gov Tracking ID: 26HB1UBU
Agency Tracking ID: 75743972132
Transaction Type: Sale
Transaction Date: 05/08/2019 01:10:07 PM EDT
Account Holder Name: Connie Welch
Transaction Amount: $1,276.75
Card Type: Visa
Card Number: **********6622

Registration Number: 92589-R
Company Name: Envyss, LLC
Company Number: 92589
Action Code: A540

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.


Pay.gov is a program of the U.S. Department of the Treasury, Bureau of the Fiscal Service

Please read instructions on reverse side before c… ing form. Form Ap… d. OMB No. 2070-0060. Approval expires 05-31-98

EPA	United States Environmental Protection Agency Washington, DC 20460	☐ Registration ☐ Amendment ☒ Other	OPP Identifier Number

Application for Pesticide – Section 1

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
92589-R	Jacqueline Hardy	☒ None ☐ Restricted
4. Company/Product (Name) **Envyss, LLC/ BioBuster**	PM# **PM-34**	
5. Name And Address Of Applicant *(Include ZIP Code)* **Envyss, LLC P.O. Box 907 Blue Ridge, GA 30513** ☐ *Check if this is a new address*	6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____	

Section II

☐ Amendment – Explain below.
☐ Resubmission in response to Agency letter dated _____
☐ Notification – Explain below.
☐ Final Printed labels in response to Agency letter dated _____
☐ "Me Too" Application.
☐ Other – Explain Below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Response to Agency letter dated August 8, 2019 re Preliminary Technical Screen

Section III

1. Material This Product Will Be Packaged In:

Child Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes* ☒ No	☐ Yes ☒ No	☐ Yes ☒ No	☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify) _
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per Container	If "Yes" Unit Packaging wgt. / No. per Cont	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☒ Label ☐ Container		☒ On Label ☒ On Labeling accompanying product

6. Manner in Which Label is Affixed to Product: ☐ Lithographed ☒ Paper glued ☐ Stenciled ☐ Other _____

Section IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Dr. Connie B. Welch-DuJardin	Authorized Representative for Envyss, LLC	(703) 754-0248 x8118

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received

2. Signature	3. Title
Dr. Connie B. Welch-DuJardin	Authorized Representative for Envyss, LLC
4. Typed Name: Dr. Connie B. Welch-DuJardin	5. Date: August 21, 2019

Please read instructions on reverse side before completing form. Form Approved. OMB No. 2070-0060, Approval expires 05-31-98

EPA	United States Environmental Protection Agency Washington, DC 20460	☒ Registration ☐ Amendment ☐ Other	OPP Identifier Number

Application for Pesticide – Section 1

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
92589-R	Jacqueline Hardy	☒ None ☐ Restricted
4. Company/Product (Name) **Envyss, LLC/ BioBuster**	PM# **PM-34**	
5. Name And Address Of Applicant *(Include ZIP Code)* **Envyss, LLC P.O. Box 907 Blue Ridge, GA 30513** ☐ *Check if this is a new address*	**6. Expedited Review.** In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____	

Section II

☐ Amendment – Explain below.
☐ Resubmission in response to Agency letter dated _____
☐ Notification – Explain below.
☐ Final Printed labels in response to Agency letter dated _____
☐ "Me Too" Application.
☐ Other – Explain Below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Application for new end use pesticide formulation.

Section III

1. Material This Product Will Be Packaged In:

Child Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes* ☒ No	☐ Yes ☒ No	☐ Yes ☒ No	☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify) _
***Certification must be submitted**	If "Yes" No. per Unit Packaging wgt. Container	If "Yes" No. per Unit Packaging wgt.	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☒ Label ☐ Container		☒ On Label ☒ On Labeling accompanying product

6. Manner In Which Label Is Affixed to Product: ☐ Lithographed ☒ Paper glued ☐ Stenciled ☐ Other _____

Section IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Dr. Connie B. Welch-DuJardin	**Authorized Repreeentative for Envyss, LLC**	**(703) 754-0248 x8118**

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received

2. Signature	3. Title
Dr. Connie B. Welch-DuJardin	**Authorized Representative for Envyss, LLC**
4. Typed Name **Dr. Connie B. Welch-DuJardin**	5. Date **May 13, 2019**

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete

Form Approved OMB Nos. [illegible]-0060; 2070-0057; 2070-0107; 2070-0122; 2070-0164

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number EnVyss, LLC	EPA Registration Number/File Symbol 92589-R
Active Ingredient(s) and/or representative test compound(s) Potassium peroxymonosulfate (PC 63604); Sodium Chloride (PC 13905)	Date August 21, 2019
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Indoor, Non-food Disinfectant, Virucide	Product Name BioBuster

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☑ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses .

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature	Date	Typed or Printed Name and Title
Dr. Connie B. Welch-DuJardin	Aug 21, 2019	Dr. Connie B. Welch-DuJardin, Authorized Agent

EPA Form 8570-34 (12-2003) Electronic and Paper versions available. Submit only Paper version.

toXcel

Toxicology & Regulatory Affairs
7140 Heritage Village Plaza
Gainesville, VA 20155-3061
USA

Phone: (703) 754-0248 **Fax: (703) 310-6950**

May 13, 2019

Jacqueline Hardy, PM 34 (REGFEE)
Registration Division (Mail Code 7510P)
US EPA / Office of Pesticide Programs
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Re: Registration Application for BioBuster, EPA File Symbol 92589-R
EPA Company Number: 92589
PRIA Category: A540

Dear Ms. Hardy:

On behalf of our client, Envyss, LLC, we are submitting a new registration application for BioBuster, EPA File Symbol 92589-R. BioBuster is a broad-spectrum disinfectant and virucide.

The following are included with this registration application package:

1. Registration Application (EPA Form 8570-1)
2. PRIA Payment Confirmation
3. Transmittal Document
4. Confidential Statement of Formula (EPA Form 8570-4)
5. Data Matrix (EPA Form 8570-35) – Public and Private versions
6. Respect for Citation of Data
7. Study data

It is anticipated that this registration application will be categorized as a PRIA A540, with a corresponding review timeframe of 5 months. A small business application is being submitted separately in support of this application.

If you have any questions or require additional information, please contact me by e-mail at Connie.Welch@toxcel.com or by phone at (703) 754-0248 x 8118.

Sincerely,

Dr. Connie B. Welch-DuJardin

Dr. Connie B. Welch-DuJardin
Vice President
Authorized Agent for Envyss, LLC

From: Melba Morrow
To: Nelson Cornwell
Subject: FW: Decision on use of viral hierarchy for animal pathogens
Date: Wednesday, May 8, 2019 11:09:52 AM

Here is the email regarding hierarchy. We followed the Agency's instructions.

From: Hardy, Jacqueline [mailto:Hardy.Jacqueline@epa.gov]
Sent: Friday, February 24, 2017 10:25 AM
To: Melba Morrow <Melba.Morrow@toxcel.com>; Perry, Mark <Perry.Mark@epa.gov>; rindal.mark@epa.gov
Cc: Connie Welch <Connie.Welch@toxcel.com>; Charles Reeves <creeves@envyss.com>; Willis, Kristen <Willis.Kristen@epa.gov>
Subject: RE: Decision on use of viral hierarchy for animal pathogens

Good Morning, Melba

The Agency has not drafted formal guidance on viral hierarchy in testing animal pathogens; however, we offer the following:

One virus from each of the 3 viral categories, should be tested:

1) Small non-enveloped- Canine parvovirus
2) Large non-enveloped- Egg Drop Syndrome (Adenovirus)
3) Enveloped- Herpes virus (avian laryngotracheitis or Marek's Disease virus)

As an alternative, the 2 hardest to kill small non-enveloped viruses which would be Canine parvovirus and feline panleukopenia may be tested.

If you have any questions, please contact me.

Regards,

Jacqueline Hardy

Jacqueline Hardy
Acting Chief, Product Science Branch
Antimicrobials Division (7510P)
U.S. Environmental Protection Agency
2777 South Crystal Drive
Arlington, VA 22202
Phone: (703) 308-6416

From: Melba Morrow [mailto:Melba.Morrow@toxcel.com]
Sent: Friday, February 24, 2017 10:04 AM
To: Hardy, Jacqueline <Hardy.Jacqueline@epa.gov>; Perry, Mark <Perry.Mark@epa.gov>; rindal.mark@epa.gov
Cc: Connie Welch <Connie.Welch@toxcel.com>; Charles Reeves <creeves@envyss.com>

Subject: Decision on use of viral hierarchy for animal pathogens

Good morning,
As a follow-up to a teleconference I had with Jacqui Hardy on February 8, 2017, I was wondering whether any written decision or guidance could be offered on the use of the viral hierarchy in testing animal pathogens? My client is in the process of securing a lab and would need to know the extent of the testing requirements for these animal pathogens so that they can budget accordingly. Any timely guidance that you can provide would be greatly appreciated.

Best,

Melba

Melba S. Morrow, DVM
Director of Toxicology
Toxcel, LLC
7140 Heritage Village Plaza
Gainesville, VA. 20155
Tel: 703-754-0248 (x120)
Fax: 703-310-6950

TRANSMITTAL DOCUMENT

1. **Name and Address of Submitter**

Envyss, LLC
7140 Heritage Village Plaza
Gainesville, VA 20155

Authorized Representative
toXcel, LLC
7140 Heritage Village Plaza
Gainesville, VA 20155

2. **Regulatory Action**
Registration application for BioBuster.
EPA Reg. No. 92589-R

3. **Transmittal Date**
13 May 2019

4. **List of Submitted Studies/Documents**

	Admin	· EPA Form 8570-1 – Application for Registration · EPA Form 8570-34 – Certification with Respect to Citation of Data · EPA Form 8570-35 – Data Matrix (Internal and Public) · Confidential Statement of Formula (EPA Form 8570-4) · PRIA Payment Confirmation
MRID 50847901	**Volume 1**	BioBuster Group A Product Chemistry. May 10, 2019; toXcel, LLC; 830.1550, 830.1600, 830.1620, 830.1850, 830.1670, 830.1700, 830.1750, 830.1800 and 830.1900; 154 pages.
MRID 50847902	**Volume 2**	BioBuster Group B Product Chemistry. May 10, 2019; toXcel, LLC; 830.6302, 830.6303, 830.6304, 830.6313, 830.6314, 830.6315, 830.6316, 830.6317, 830.6319, 830.8320, 830.6321, 830.7000, 830.7100, 830.7200, 630.7220, 830.7300, 830.7370, 830.7550, 830.7840 and 830.7950; 24 pages.
MRID 50847903	**Volume 3**	AOAC Use Dilution Test – *Aeromonas hydrophila*; May 1, 2018; Microbac Laboratories, Inc.; Laboratory Project Identification Number 962-109; OPPTS 810.2200; 26 pages.
MRID 50847904	**Volume 4**	Virucidal Hard-Surface Efficacy Test – Bovine Viral Diarrhea Virus; April 18, 2018; Microbac Laboratories, Inc.; Laboratory Project Identification Number 962-101; OPPTS 810.2200; 30 pages.
MRID 50847905	**Volume 5**	Virucidal Hard-Surface Efficacy Test – Canine Parvovirus; April 30, 2018; Microbac Laboratories, Inc.; Laboratory Project Identification Number 962-102; OPPTS 810.2200; 31 pages.
MRID 50847906	**Volume 6**	AOAC Use Dilution Test – *Listeria monocytogenes*; May 1, 2018; Microbac Laboratories, Inc.; Laboratory Project Identification Number 962-106; OPPTS 810.2200; 26 pages.

MRID 50847907	**Volume 7**	AOAC Use Dilution Test – *Streptococcus pneumoniae*; May 1, 2018; Microbac Laboratories, Inc.; Laboratory Project Identification Number 962-111; OPPTS 810.2200; 27 pages.
MRID 50847908	**Volume 8**	Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces – Virus: Avian Influenza A (H5N1) virus; June 15, 2018; Accuratus Lab Services; Project Number A25565; OPPTS 810.2200; 29 pages.
MRID 50847909	**Volume 9**	AOAC Use Dilution Test – *Campylobacter jejuni*; May 9, 2018; Microbac Laboratories, Inc.; Laboratory Project Identification Number 962-103; OPPTS 810.2200; 27 pages.
MRID 50847910	**Volume 10**	AOAC Use-Dilution Method – *Bordetella avium* (ATCC 35086); June 18, 2018; Accuratus Lab Services; Project Number A25531; OPPTS 810.2200; 30 pages.
MRID 50847911	**Volume 11**	AOAC Use-Dilution Method – *Bordetella bronchiseptica* (ATCC 10580); June 18, 2018; Accuratus Lab Services; Project Number A25532; OPPTS 810.2200; 30 pages.
MRID 50847912	**Volume 12**	AOAC Use-Dilution Method – *Escherichia coli* O157:H7 (ATCC 35150); June 18, 2018; Accuratus Lab Services; Project Number A25533; OPPTS 810.2200; 30 pages.
MRID 50847913	**Volume 13**	Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces – Feline Infectious Peritonitis virus; June 14, 2018; Accuratus Lab Services; Project Number A25566; OPPTS 810.2200; 29 pages.
MRID 50847914	**Volume 14**	AOAC Use-Dilution Method – *Xanthomonas compestris* (ATCC 11058); June 18, 2018; Accuratus Lab Services; Project Number A25530; OPPTS 810.2200; 30 pages.
MRID 50847915	**Volume 15**	AOAC Use-Dilution Method – *Pseudomonas aeruginosa* (ATCC 15442); May 17, 2018; Accuratus Lab Services; Project Number A25297; OPPTS 810.2200; 34 pages.
MRID 50847916	**Volume 16**	AOAC Use-Dilution Method – *Salmonella enterica* (ATCC 10708); May 21, 2018; Accuratus Lab Services; Project Number A25299; OPPTS 810.2200; 32 pages.
MRID 50847917	**Volume 17**	AOAC Use-Dilution Method – *Staphylococcus aureus* (ATCC 6538); April 30, 2018; Accuratus Lab Services; Project Number A25298; OPPTS 810.2200; 32 pages.
MRID 50847918	**Volume 18**	AOAC Use-Dilution Method – *Streptococcus suis* (ATCC 43765); June 18, 2018; Accuratus Lab Services; Project Number A25534; OPPTS 810.2200; 30 pages.
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MRID 50847923	**Volume 23**	Evaluation of Bactericidal Disinfectant Efficacy on Hard Non-Porous Surfaces Against *Vibrio anguillarum* on Bio-

MRID 50847924 **Volume 24**

Buster; July 31, 2018; Eurofins – Biolab S.R.L.; Report No. S-2018-00334 AM; OPPTS 810.2200; 22 pages.
Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces – Infectious Laryngotracheitis Virus; August 14, 2018; Accuratus Lab Services; Project No. A25567; OPPTS 810.2200; 35 pages.

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21-Day Screen Completed by Contractor

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Content Screen: Recommend to Pass/Fail

11-3 Review: Pass/Fail/NA

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